

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

Clinical Condition: Renal Cell Carcinoma Staging

Variant 1: Tumor ≤ 3 cm.

| Radiologic Procedure | Rating | Comments | RRL* |
|---|--------|--|----------------------------------|
| CT abdomen without and with contrast | 9 | Should include precontrast and postcontrast phases, including arteriographic phase. Multiplanar reconstructions and 3D volume-rendered images are helpful for surgical planning. | ☼ ☼ ☼ ☼ |
| X-ray chest | 8 | Asymptomatic patient. | ☼ |
| MRI abdomen without and with contrast | 8 | See statement regarding contrast in text under "Anticipated Exceptions." | O |
| CT chest without contrast | 5 | Patient with solitary nodule on chest radiograph or respiratory symptoms. | ☼ ☼ ☼ |
| US abdomen | 4 | More appropriate in patients with contrast sensitivity or renal insufficiency. | O |
| MRI head with or without contrast | 1 | | O |
| FDG-PET whole body | 1 | | ☼ ☼ ☼ ☼ |
| Tc-99m bone scan whole body | 1 | | ☼ ☼ ☼ |
| Arteriography kidney | 1 | | ☼ ☼ ☼ |
| Venacavography inferior | 1 | | ☼ ☼ ☼ |
| X-ray radiographic survey whole body | 1 | | ☼ ☼ ☼ |
| Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate | | | *Relative Radiation Level |

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

| Radiologic Procedure | Rating | Comments | RRL* |
|---|---------------|--|----------------------------------|
| CT abdomen without and with contrast | 9 | Should include precontrast and postcontrast, including arteriographic phase. Multiplanar reconstructions and 3D volume-rendered images are helpful for surgical planning. | ☼☼☼☼ |
| X-ray chest | 8 | | ☼ |
| CT chest without contrast | 8 | Can identify subtle pulmonary nodules, mediastinal lymphadenopathy, bone and subcutaneous metastases. Confirms or excludes metastases seen on chest radiograph. | ☼☼☼ |
| MRI abdomen without and with contrast | 8 | See statement regarding contrast in text under "Anticipated Exceptions." | O |
| FDG-PET whole body | 4 | | ☼☼☼☼ |
| US abdomen | 3 | | O |
| Venacavography inferior | 3 | | ☼☼☼ |
| Tc-99m bone scan whole body | 3 | More appropriate if tumor >7 cm or locally advanced; if bone pain present. | ☼☼☼ |
| MRI head with or without contrast | 3 | More appropriate if tumor >7 cm or locally advanced; or if neurologic symptoms present. | O |
| 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. | ☼☼☼ |
| X-ray radiographic survey whole body | 1 | | ☼☼☼ |
| Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate | | | *Relative Radiation Level |

RENAL CELL CARCINOMA STAGING

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Summary of Literature Review

Renal cell carcinoma (RCC) accounts for 2%-3% of all visceral malignancies. It is estimated that approximately 51,000 new cases are diagnosed per year in the U.S., resulting in approximately 12,890 deaths [1]. The incidence in men is 1.6 times greater than 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 [4,5].

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 [6]. 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 [7-10].

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 TNM staging system (Appendixes 2 and 3), which is regarded as more accurate and of greater prognostic value [8,10]. Significant changes from the 1987 and 1997 versions of the TNM system reflect the importance of tumor size and the extent of inferior vena cava (IVC) involvement. Tumors larger than 7 cm were 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 branches (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.

In the past, renal cancers were larger and more likely to be symptomatic at discovery, 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, as many more tumors are identified serendipitously on cross-sectional imaging, those presenting with stage I-II disease may reach 71%-75% [2,3]. 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 [8,11].

Prognosis is related to the size of the primary tumor as well as stage. In one large study, patients with tumors <5 cm in diameter had a 65% 5-year survival rate, whereas tumors >10 cm in diameter yielded a median survival rate of 37% at 5 years [12]. 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 [2,3] nonaggressive biologic behavior cannot be assumed. In one study of 50 lesions <3 cm in diameter, 38% had extension outside the renal capsule with T3/T4 disease [13]. 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, although false positives can be problematic [14-16]. 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 [15,16]. In one series of 186 patients whose tumors were staged as T1 at CT, 31% were found to have pathologically T3a lesions with microscopic invasion of fat in Gerota's fascia. Their recurrence-free survival rate,

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however, was the same as that of the patients who had pathologically confirmed T1 lesions [17]. 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 [18]. In a study of 73 RCCs, Roy et al [19] showed that the presence of a pseudocapsule on MRI had an accuracy of 93% for clear-cell carcinoma in separating T1/T2 tumors from T3a tumors.

CT shows a 100% negative predictive value for T3a disease involving the adrenal gland [20]. Tsui et al [11] demonstrated that CT missed adrenal abnormalities in only three of 511 patients with histologically proven adrenal involvement.

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 [21]. 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.

Venous thrombus in the renal vein or IVC can usually be identified on an initial diagnostic CT, but if findings are equivocal, MRI may become necessary. 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 [22]. Multi-detector-row CT shows very high accuracy rates, achieving equivalence with MRI [14,23]. 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 [14-16,23]. 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 [14-16,23,24]. 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. Diagnostic accuracy is improved with gadolinium-enhanced MR venography [24]. The

highest sensitivity and specificity in assessing venous involvement are achieved with gradient echo sequence [16,25]. 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 enhancement. Laissy et al [24] achieved 89% sensitivity and 96% specificity in using gadolinium-enhanced MR venography to determine whether tumor thrombus or bland thrombus was present in 12 patients confirmed at surgery. More recently, in a larger study, Ergen et al [25] correctly diagnosed 22 patients with tumor thrombus and 6 patients with bland thrombus. 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 color duplex sonography, which can be as accurate as MRI or CT in identifying the cephalad extent of a tumor thrombus [26]. US is limited, however, 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.

Cavography is approximately 85%-100% sensitive for detecting caval thrombus and is equal to MRI in accuracy [21,27]. However, multidetector, multiphase CT or MRI suffices to diagnose caval thrombus, and thus catheter cavography is rarely needed.

Angiography has proved insensitive for tumor thrombus [28]. 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 [22,29,30]. All imaging is suboptimal for N staging because of the reliance on node size for assessing metastases [25]. 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. A small pilot study by Guimares et al [31] showed 100% sensitivity and 95.7% specificity. 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 [14-16].

The presence of T4M0-1 disease (metastatic disease with contiguous invasion) is also important information for 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% [30]. The multiplanar capabilities of MRI can be useful in this regard; however, neither technique always assesses liver or diaphragmatic invasion correctly [32,33]. Angiography can also be misleading, since tumors can recruit vessels from the liver or elsewhere without the tumor actually invading the organ.

T4NxM1 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 [2,13,34] 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 [35].

Similarly, neither routine bone scans nor bone surveys appear routinely justified [36]. However, if the patient has an elevated alkaline phosphatase, bone pain, or an extremely large and aggressive tumor, bone scans may be helpful [36,37]. 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 [38].

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 [39,40]. 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 (≤ 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 used.

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 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 could be incorporated into any staging study of the renal cancer, as the vascular information can be helpful to surgeons in planning a resection. This is especially true for tumors in solitary kidneys and for centrally located tumors. Catheter angiography can be performed to embolize large tumors prior to resection [41-44].

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/1.73m²), 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/1.73m². For more information, please see the [ACR Manual on Contrast Media](#) [45].

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® [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® Overview](#)
- [Procedure Contrast 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. 2002 Revision of the TNM System for Staging Renal Cell Carcinoma [9]

Primary tumor (T)

| Stage | Sub-Stage | Definition |
|-------|-----------|---|
| T1 | | Tumor 7 cm or less in greatest dimension, limited to kidney |
| | T1a | Tumor 4 cm or less in greatest dimension, limited to kidney |
| | T1b | Tumor >4 cm but not more than 7 cm in greatest dimension, limited to kidney |
| T2 | | Tumor > 7 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 vena cava below the diaphragm |
| | T3c | Tumor grossly extends into vena cava above 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 metastases |
| N1 | | Metastases in 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 |
| | T3a, N0, M0 |
| | T3a, N1, M0 |
| | T3b, N0, M0 |
| | T3b, N1, M0 |
| | T3c, N0, M0 |
| T3c, N1, M0 | |
| Stage IV | T4, N0, M0 |
| | T4, N1, M0 |
| | Any T, N2, M0 |
| | Any T, any N, M1 |