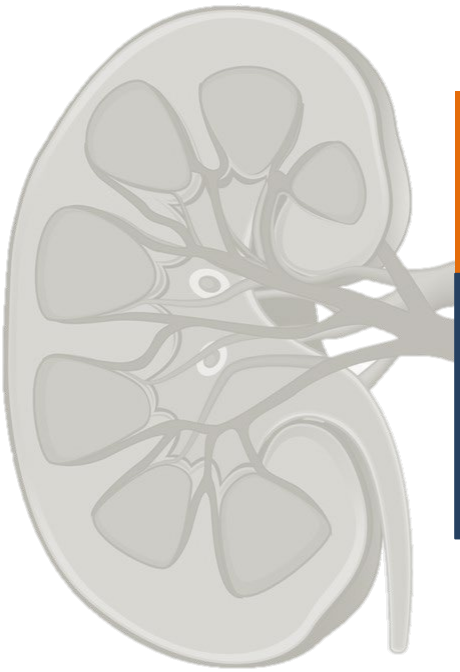


Roadmap for Management of

Patients with T1 Renal Masses

Version 1

MUSIC
Michigan Urological Surgery Improvement Collaborative

KIDNEY
Kidney mass: Identifying & Defining Necessary Evaluation & Therapy

Making Michigan #1 in Urologic Care

Roadmap for Management of Patients with T1 Renal Masses

In our efforts to continuously improve quality of care for patients in Michigan with urologic conditions, the Michigan Urological Surgery Improvement Collaborative (MUSIC) has developed a systematic approach for management of patients with T1 renal masses (≤7 cm in size). These masses may contain cancerous cells, and we hope that each patient will receive the care they need whether it is determined that they have kidney cancer or not.

This roadmap outlines an approach to management of patients with T1 renal masses that was developed in the MUSIC collaborative. Recommendations within this roadmap were derived from a modified Delphi approach to obtain consensus from a panel of 26 MUSIC urologists and/or data from the initial 1500+ patients evaluated within a MUSIC-KIDNEY practice.

This approach divides care into two distinct phases:

1) **Evaluation Phase: Steps to take while considering management options**
2) **Surveillance Phase: A roadmap for how to perform surveillance**

*This document is not intended for patients with renal masses >7 cm in size, higher stage renal cancer, or cancer of the renal pelvis (urothelial carcinoma). For these patients, definitive treatment is recommended; individual discussions will be necessary to determine the best course of action for each patient.

Introduction

Management Phases for Patients with T1 Renal Masses

MUSIC's roadmap for patients with T1 renal masses divides the management process into two distinct phases: The **Evaluation Phase** and the **Surveillance Phase**.

Evaluation Phase

Steps to take while considering management options

Step 1: Obtain appropriate testing

Step 2: Estimate life expectancy

Step 3: Determine appropriateness for surveillance

Step 4: Engage in shared-decision making

Surveillance Phase

How to perform surveillance

Step 1: Select surveillance plan

Step 2: Monitor disease longitudinally

Step 3: Assess need for transition to other treatment(s)

Management Phases for Patients with T1 Renal Masses

Evaluation Phase

The Evaluation Phase involves four important steps to determine whether to pursue immediate treatment or initial surveillance:

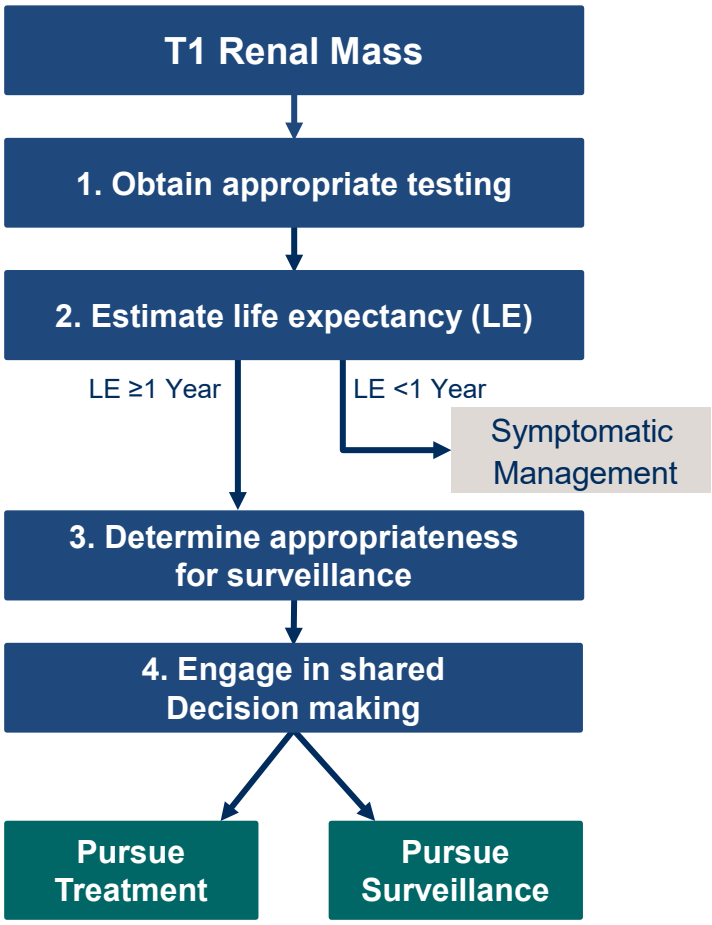
Step 1: Obtain appropriate testing

Step 2: Estimate life expectancy (LE)

Step 3: Determine appropriateness for surveillance based on MUSIC criteria*

Step 4: Engage in shared-decision making regarding management

*Some patients will choose treatment at this point based on preference or uncertainty around appropriateness for surveillance.



Evaluation Phase: Steps to Take While Considering Management Options

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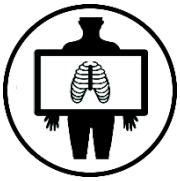
Step 1: Appropriate Testing

CT with & without contrast OR Multiphase MRI

(consider additional imaging if indeterminate after first study)



Chest Imaging for > 3cm; prefer CT thorax for >5cm

Baseline Assessment: CBC, CMP, UA (consider ACR)

Consider Renal Mass Biopsy*
***for solid, accessible masses**

Evaluation Phase: Obtain Appropriate Imaging

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Step 1: Appropriate Testing

CT with and without Contrast or Multiphase MRI

- If initial imaging is indeterminate, consider additional studies
- Contrast media and kidney function
  - Iodinated Contrast Media
    - Benefits likely outweigh risks when eGFR>30
  - Group II Gadolinium-based Contrast Media
    - Benefits likely outweigh risks for all eGFR levels
- Documentation of tumor complexity is recommended

	1 Point	2 Point	3 Point	Total
R	Small (T1a)	In between (T1b)	Big (T2)	_____(R Point)
E	Mostly **exo**phytic	In between	Mostly all **endo**phytic	_____(E Point)
N	Cortical	Collecting system **may** be entered during PN	Collecting system **will** be entered during PN	_____(N Point)
L	Polar	In between	At hilum	_____(L Point)

Complexity Total = Sum of all Points (R+E+N+L)

Low: 4-6	Intermediate: 7-9	High: 10-12

Evaluation Phase: Obtain Appropriate Imaging

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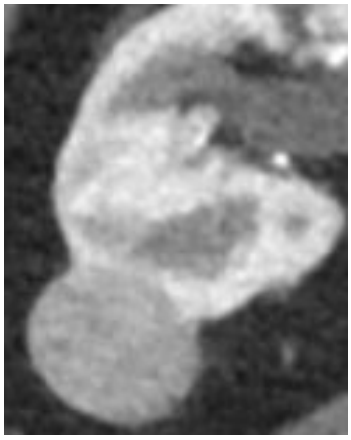
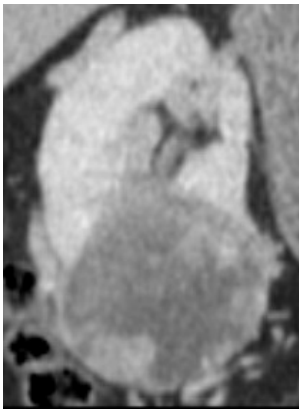
Step 1: Appropriate Testing

Renal Mass Imaging Examples

	Low Complexity	High Complexity
Small	 1.9 cm RENL = 4	 1.6 cm RENL = 10
Medium	 3.1 cm RENL = 5	 4.2 cm RENL = 10
Large	 5.0 cm RENL = 6	 6.9 cm RENL = 10

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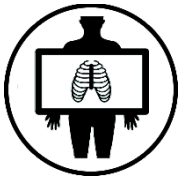
Step 1: Appropriate Testing



Chest Imaging for Masses >3cm

MUSIC KIDNEY Chest Imaging Appropriateness Criteria	
Renal Mass Size	**Recommendation**
≤ 3 cm	Optional (CT not indicated)
3.1 - 5 cm	Recommended (X-Ray preferred)
> 5 cm	Required (CT preferred)

Evaluation Phase: Obtain Appropriate Imaging

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Step 1: Appropriate Testing

Consider Renal Mass Biopsy*
*for solid, accessible masses

- Strong rationale for individuals in whom biopsy findings will change management
- Provides a definitive diagnosis in 80% to 90% of cases
- Outpatient procedure (8% are admitted to the hospital)
- Low complication rate (3% are seen in ED following biopsy)
- Coaxial sheath is used to prevent spread of cancer
- Assignment of subtype and grade of RCC increase with the use of immunohistochemical and other molecular analyses

Evaluation Phase: Obtain Appropriate Imaging

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Step 2: Estimate Life Expectancy

LIFE EXPECTANCY TOOL FOR KIDNEY CANCER

This instrument allows you to determine a patient's estimated years of life remaining, accounting for common comorbidities.

Step 1. Calculate the CVI score (range: 0-6) by assigning points as follows

Points	Condition
2	Congestive heart failure
1	Chronic kidney disease Chronic obstructive pulmonary disease Cerebrovascular disease Peripheral vascular disease

Step 2. Use the tables on the next page to categorize each T1 renal mass patient (stage I) as having an estimated life expectancy that is >10 years, between 6 and 10 years, between 1 and 5 years, or less than 1 year (symptomatic management is recommended).

For more detailed information or for patients with a T2+ renal mass (stage II-IV), scan the QR code or go to
https://ask.musicurology.com/for-doctors/kidney-cancer-resources-for-doctors/

Evaluation Phase: Estimate Life Expectancy

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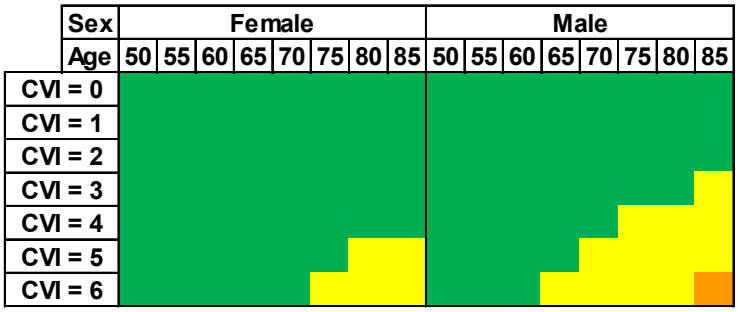
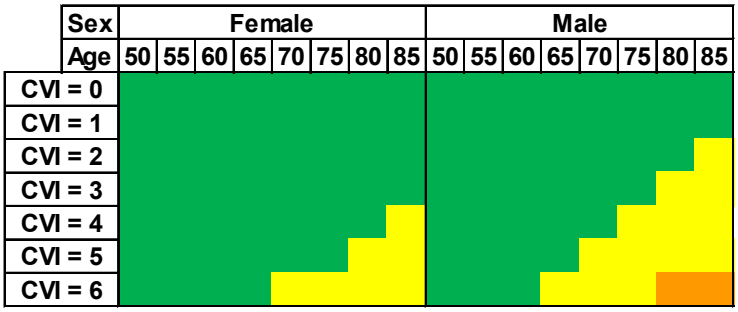
Step 2: Estimate Life Expectancy

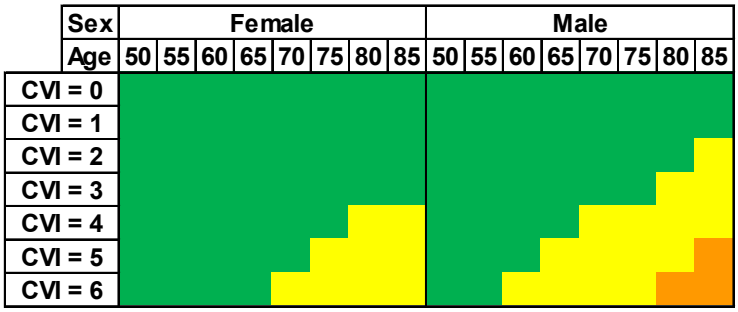
2cm Renal Mass



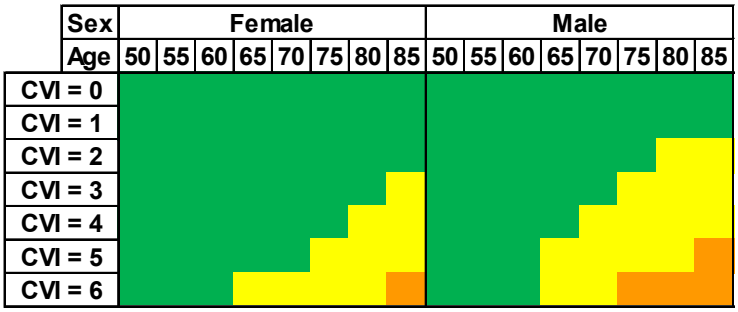
3cm Renal Mass



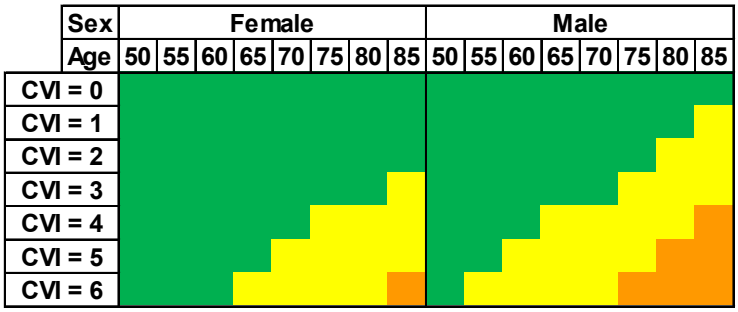
4cm Renal Mass



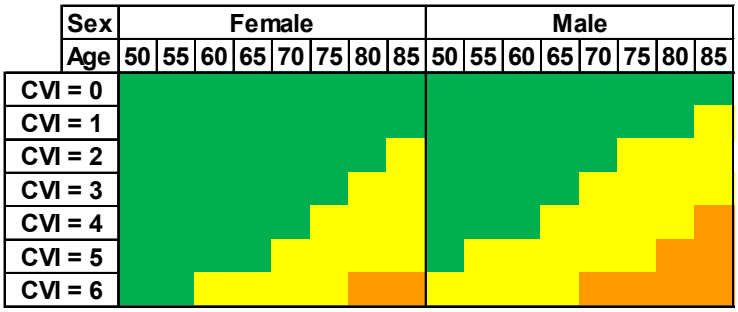
5cm Renal Mass



6cm Renal Mass



7cm Renal Mass



= Life Expectancy >10 years = Life Expectancy 6-10 years = Life Expectancy 1-5 years

Evaluation Phase: Estimate Life Expectancy

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Step 2: Estimate Life Expectancy

Malignant and Metastatic Potential by Tumor Size

Renal Mass Size (cm)	Likelihood of Cancer[1-3]	Metastasis at Presentation[1,4]	Metastasis during Follow-up[1]
0.1 – 1.0	50-68%	0%	0%
1.1 – 2.0	75-81%	0-1%	0%
2.1 – 3.0	79-89%	0-1%	3%
3.1 – 4.0	81-89%	1-2%	3%
4.1 – 5.0	88%	3-4%	13%
5.1 – 6.0	87-91%	4-7%	18%
6.1 – 7.0	92-93%	6-7%	24%

[1]Umbreit, EC et al. Metastatic potential of a renal mass according to original tumour size at presentation. BJUI 2011; 109: 190-194.
[2]Bhindi, B et al. The probability of aggressive versus indolent histology based on renal tumor size: implications for surveillance and treatment. European Urology 2018; 74: 489-497.
[3]Patel, HD et al. Surgical removal of renal rumors with low metastatic potential based on clinical radiographic size: a systematic review of the literature. Urologic Oncology 2019; 37: 519-524.
[4]Daugherty, M et al. The metastatic potential of renal tumors: influence of histologic subtypes on definition of small renal masses, risk stratification, and future active surveillance protocols. Urologic Oncology 2017; 35: 153.e15-153.e20.

Step 3: Determine Appropriateness for Surveillance Based on MUSIC Criteria

Surveillance Exclusion Criteria

- Radiologic suspicion of T3 disease or infiltrative features
- Renal mass biopsy showing grade 4 renal cell carcinoma (RCC)
- Renal mass biopsy showing the following histotypes:
  - Collecting duct carcinoma
  - Renal medullary carcinoma
  - Rhabdoid variant of RCC
  - Sarcoma
  - Sarcomatoid RCC

Evaluation Phase: Determine Surveillance Appropriateness Based on MUSIC Criteria

Step 3: Determine Appropriateness for Surveillance Based on MUSIC Criteria

Using initial imaging and life expectancy results, evaluate a patient's appropriateness for Surveillance as established by the MUSIC Consensus Panel.

	<3 cm	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
<1 year						
1-5 years						
6-10 years						
>10 years						

= Appropriate for Surveillance = Uncertain = Inappropriate for Surveillance

Evaluation Phase: Determine Surveillance Appropriateness Based on MUSIC Criteria

Step 3: Determine Appropriateness for Surveillance Based on MUSIC Criteria

Additional Details re: Appropriateness for Surveillance Based on MUSIC Criteria

This placard is used to present the MUSIC appropriateness panel recommendations for Surveillance for different clinical scenarios considered by the panel. Scenarios differed based on tumor size, tumor complexity, patient life expectancy, comorbidities, renal function, and ease of nephron-sparing treatment. All patients with renal mass <3 cm are considered to be appropriate candidates for Surveillance. All patients with a life expectancy <1 year should be considered for symptomatic management.

Otherwise healthy, ***Low*** Complexity

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Otherwise healthy, ***Intermediate*** Complexity

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Otherwise healthy, ***High*** Complexity

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Elevated Perioperative Risk, ***Low*** Complexity

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Elevated Perioperative Risk, ***Intermediate*** Complexity

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Elevated Perioperative Risk, ***High*** Complexity

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Nephron-Sparing Candidate, eGFR = 15-29

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Nephron-Sparing Candidate, eGFR = 30-44

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Nephron-Sparing Candidate, eGFR = 45-60

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Not Nephron-Sparing Candidate, eGFR = 15-29

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Not Nephron-Sparing Candidate, eGFR = 30-44

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Not Nephron-Sparing Candidate, eGFR = 45-60

	3-3.9 cm	4-4.9 cm	5-5.9 cm	6-6.9 cm	7+ cm
1-5 years					
6-10 years					
>10 years					

Step 4: Engage in Shared-Decision Making

Step 4: Once imaging results are complete, life expectancy has been calculated, and surveillance appropriateness has been assessed, engage in shared-decision making. At this point, the conversation should focus on the merits of definitive treatment and of surveillance based on the full set of information.

	Surveillance	Ablation	RPN	OPN	MIRN
Cancer Control	Fair	Good	Better	Better	Best
Renal Function	Best	Better	Better	Better	Fair
Morbidity	Best	Better	Good	Fair	Good

Evaluation Phase: Shared Decision Making

	Advantages	Disadvantages	Main Indications
Surveillance	• Least invasive and most kidney-sparing of all strategies • Most SRMs have limited oncologic potential and can be safely managed with initial short interval follow-up imaging	• Tumor remains in place and untreated • Oncologic nature of tumor is unknown (without biopsy)	• Smaller tumors • Limited life expectancy • Poor surgical candidates
Ablation	• Kidney-sparing approach with renal functional benefits (vs. RN) • Performed outside of OR (percutaneous) • For small (<3 cm) tumors, provides comparable control of metastasis to PN and RN	• Relatively high rate of local failure (~10%) • Imprecision of histopathologic diagnosis • Increased and challenges of radiographic follow-up	• Prior ipsilateral surgery for renal tumor • Poorer surgical candidates and those unwilling to undergo surveillance
Robotic Partial Nephrectomy (RPN)	• Kidney-sparing surgery with preservation of renal function when warm ischemia kept to limited duration (<20 to 25 min) • Minimally invasive surgery, with decreased pain, morbidity, and convalescence compared to OPN	• Higher complication rate for high complexity tumors and in less-experienced hands • Positive surgical margins and local recurrence rates may be higher in such situations	• Most common surgery for T1RM • Best for low to moderate (and selected high) complexity tumors
Open Partial Nephrectomy (OPN)	• Oncologic outcomes appear similar to RN • Maximizes renal functional preservation when performed with precise tumor excision and judicious use of cold ischemia	• Morbidity of flank incision (increased hospital stay, longer recovery, chance of flank bulge)	• Select patients with moderate to high-complexity tumors
Minimally-Invasive Radical Nephrectomy (MIRN, RN)	• Reproducible and effective surgery for most localized renal tumors • Minimally invasive surgery, with decreased pain, morbidity and convalescence compared to ORN (and OPN)	• Many tumors up to 7 cm can be treated with PN • Renal functional implications of removing entire kidney (average 35% decrease in GFR)	• Medium to large tumors (up to 10-12 cm) • High tumor complexity • Renal fxn good enough for GFR to remain >45 after RN

Surveillance Phase

After the Evaluation Phase, many patients will decide to pursue Surveillance. At this point, patients enter the Surveillance Phase, which involves regular follow-up evaluations and testing to monitor for changes in the risk of the cancer. The specific evaluations at each follow-up may include repeat abdominal and chest imaging, renal function assessment, renal mass biopsy, etc.

The goal of this section is to provide a **roadmap for how to perform surveillance**.

Surveillance Phase Components

Urologic Assessment

Repeat Imaging

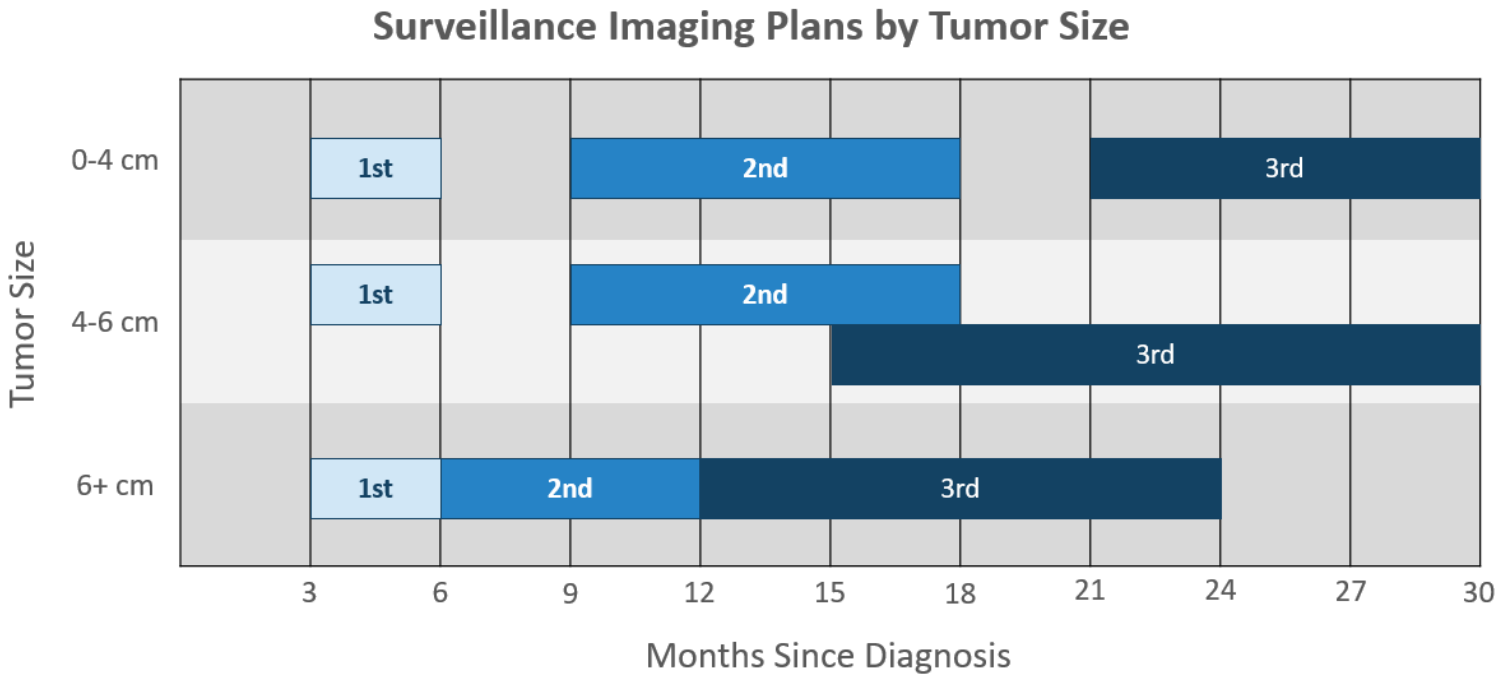
Renal Function Assessment

This document outlines the appropriate follow-up testing components and timing. The exact frequency and types of follow-up testing are based on clinical parameters and patient preferences, guided by the urologist's opinion and experience. Both surveillance plans are distinctly different from Symptomatic Management, which involves only clinical examinations.

Surveillance Phase

Surveillance Phase

MUSIC recommends that all patients on Surveillance for a renal mass receive follow-up abdominal imaging and renal function assessments at regular intervals. Interval ranges suggested by members of the MUSIC panel are presented below. The exact intervals should be decided by the urologist and patient depending on tumor size, growth rate, patient comorbidities, risk tolerance, etc.



Surveillance Phase: How to Perform Surveillance

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Step 1 & 2: Select surveillance plan and Monitor disease longitudinally

High Intensity vs Low Intensity Surveillance

High Intensity Surveillance Plan

Tumor Size	1st Surveillance Imaging	2nd Surveillance Imaging	3rd Surveillance Imaging
0 - 4 cm	3 months after diagnosis	9 months after dx (6mo after previous imaging)	21 mo after dx (12mo after previous)
4 - 6 cm			15 mo after dx (6mo after previous)
> 6 cm		6 months after dx (3mo after previous)	12 mo after dx (6mo after previous)

Low Intensity Surveillance Plan

Tumor Size	1st Surveillance Imaging	2nd Surveillance Imaging	3rd Surveillance Imaging
0 - 4 cm	6 months after diagnosis	18 months after dx (12mo after previous imaging)	30 mo after dx (12mo after previous imaging)
4 - 6 cm			
> 6 cm		12 months after dx (6mo after previous)	24 mo after dx (12mo after previous)

Step 3: When to Consider Additional Testing or Transition to Treatment for Patients on Surveillance

Scenarios That Should Prompt Further Investigation	Recommended Response
Changes in patient life expectancy and/or tumor size/stage	Re-evaluate appropriateness for continued surveillance vs. transition to treatment (see pages 10-11)
Renal Masses > 5cm	Follow-up chest imaging along with repeated abdominal imaging and renal function assessments
Rapid Tumor Growth	Likely transition to treatment; if still considering surveillance, offer renal mass biopsy
Clinical Suspicion for Local Progression or Metastatic Disease	Imaging of appropriate areas
Patient Preference	Modify intensity of surveillance or transition to treatment for sustained changes in patient preferences

Surveillance Phase: When to Perform Additional Test(s)

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For additional information regarding this brochure or the Michigan Urological Surgery Improvement Collaborative, please contact us at:

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