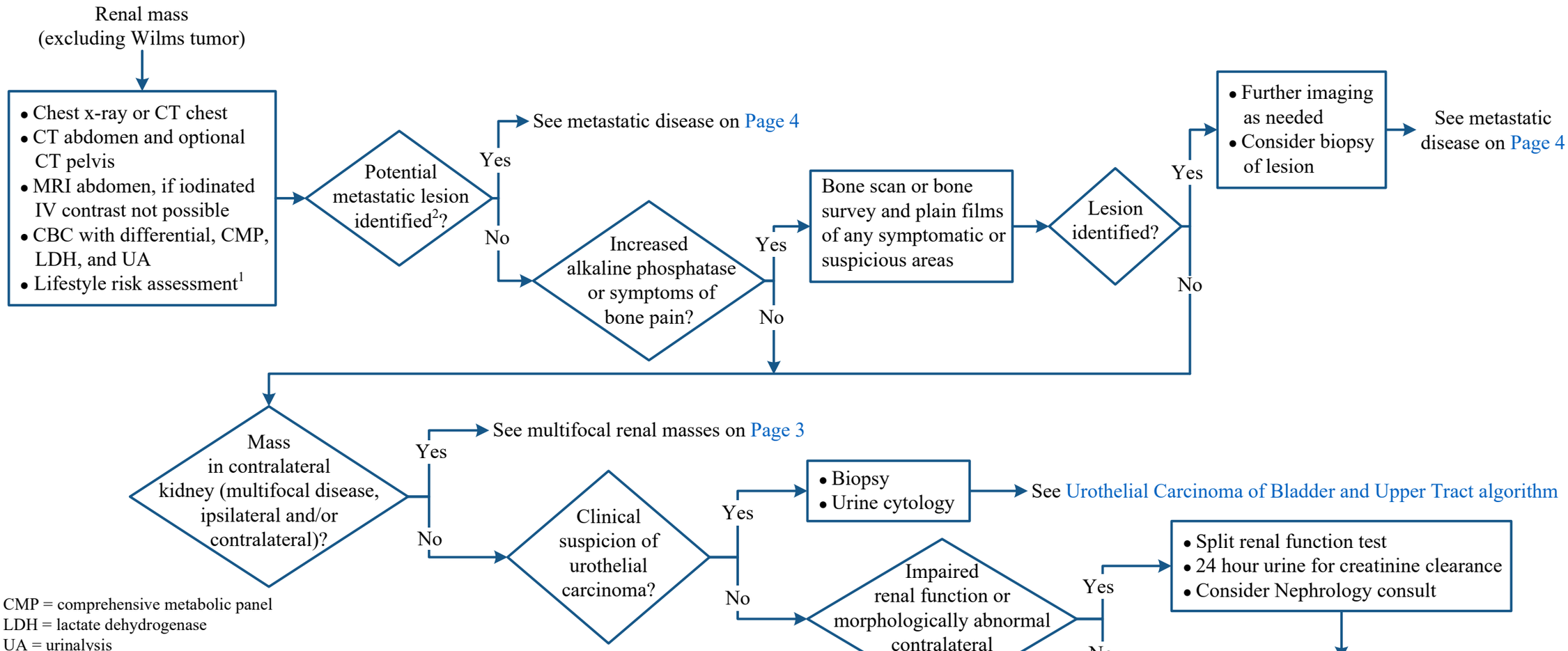
Renal Cell Carcinoma

Note: Consider Clinical Trials as treatment options for eligible patients.

Patients with renal cell carcinoma (RCC) diagnosed before age 46, regardless of histology, should be referred for genetic counseling and consideration of hereditary RCC syndromes.

INITIAL EVALUATION



CMP = comprehensive metabolic panel
LDH = lactate dehydrogenase
UA = urinalysis

[1] See Physical Activity, Nutrition, and Tobacco Cessation algorithms; ongoing reassessment of lifestyle risks should be a part of routine clinical practice

[2] Retroperitoneal lymph nodes up to 3 cm do not imply unresectable disease. Lymph node biopsy not indicated.

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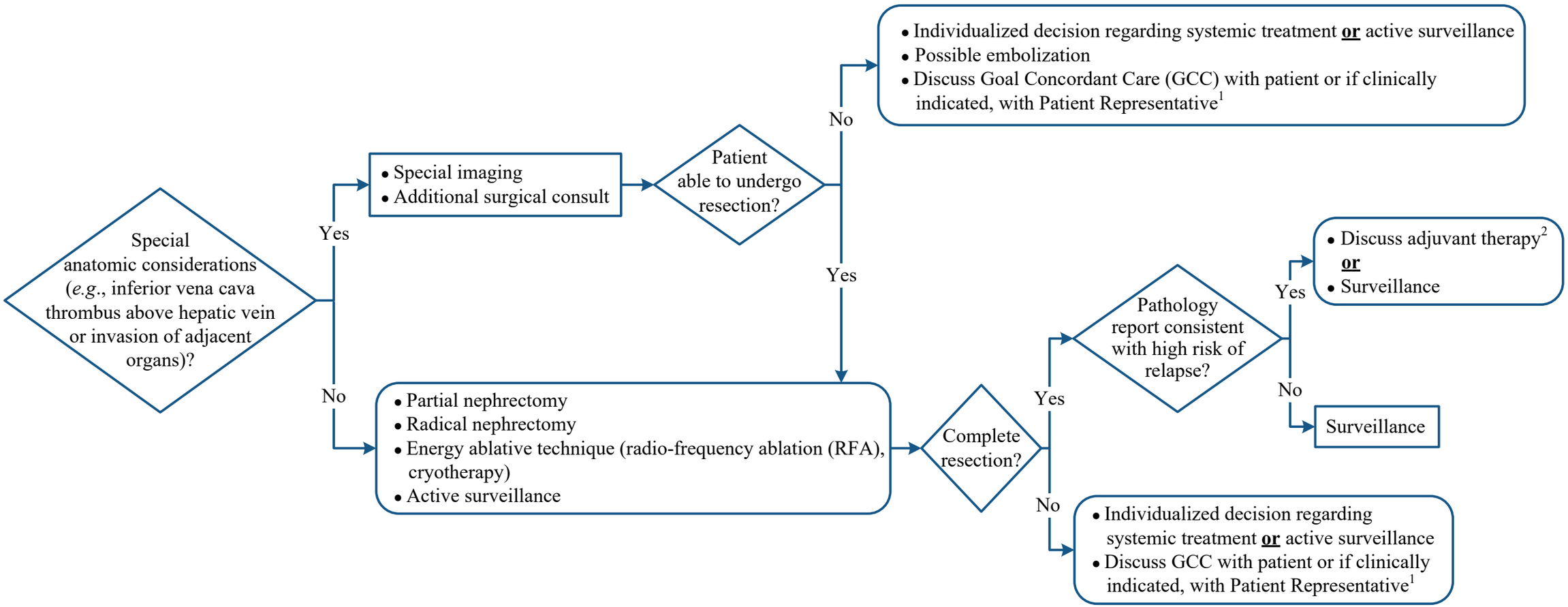
Renal Cell Carcinoma

Note: Consider Clinical Trials as treatment options for eligible patients.

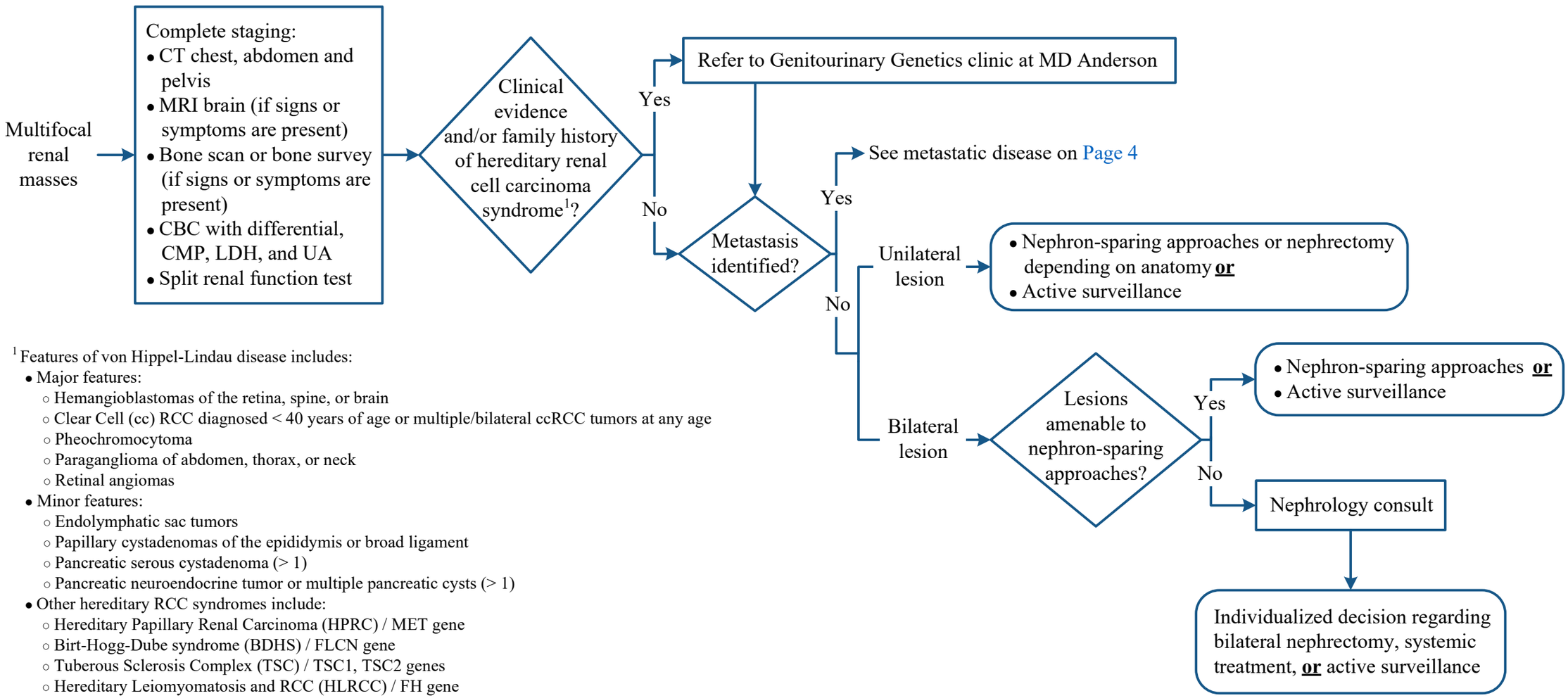


[1] GCC should be initiated by the Primary Oncologist. If Primary Oncologist is unavailable, Primary Team/Attending Physician to initiate GCC discussion and notify Primary Oncologist. Patients, or if clinically indicated, the Patient Representative should be informed of therapeutic and/or palliative options. GCC discussion should be consistent, timely, and re-evaluated as clinically indicated. The Advance Care Planning (ACP) note should be used to document GCC discussion. Refer to GCC home page (for internal use only).

[2] For stage III clear cell carcinoma, consider clinical trial or adjuvant pembrolizumab up to a year

Renal Cell Carcinoma

Note: Consider Clinical Trials as treatment options for eligible patients.



[1] Features of von Hippel-Lindau disease includes:
- Major features:
  - Hemangioblastomas of the retina, spine, or brain
  - Clear Cell (cc) RCC diagnosed < 40 years of age or multiple/bilateral ccRCC tumors at any age
  - Pheochromocytoma
  - Paraganglioma of abdomen, thorax, or neck
  - Retinal angiomas
- Minor features:
  - Endolymphatic sac tumors
  - Papillary cystadenomas of the epididymis or broad ligament
  - Pancreatic serous cystadenoma (> 1)
  - Pancreatic neuroendocrine tumor or multiple pancreatic cysts (> 1)
- Other hereditary RCC syndromes include:
  - Hereditary Papillary Renal Carcinoma (HPRC) / MET gene
  - Birt-Hogg-Dube syndrome (BDHS) / FLCN gene
  - Tuberous Sclerosis Complex (TSC) / TSC1, TSC2 genes
  - Hereditary Leiomyomatosis and RCC (HLRCC) / FH gene
  - BAP1 Tumor Predisposition Syndrome (TPDS) / BAP1 gene
  - Hereditary Paraganglioma / Pheochromocytoma (PCL/PCC) syndromes / SDHA/B/C/D genes

Renal Cell Carcinoma

Note: Consider Clinical Trials as treatment options for eligible patients.

CLINICAL PRESENTATION

Suspicion of metastatic disease

Staging:
- CT chest, abdomen, and pelvis
- CBC with differential, CMP, LDH, and UA
- MRI brain if clinically indicated
- Bone scan or bone survey if clinically indicated

METASTASES AT PRESENTATION OR RECURRENCE

A

Multiple metastases

Anatomically threatening (*e.g.*, brain lesion, imminent pathologic fracture, or biliary obstruction)?

Yes

Consider appropriate consultations:
- Surgery
- Radiation therapy
- Energy ablation
- Embolization

No

- Consider cytoreductive nephrectomy if primary tumor in place, after appropriate multidisciplinary discussion
- Biopsy if not surgical candidate

Refer to systemic regimens on Pages 5-6

Solitary metastasis

Metastasis surgically resectable?

No

Consider local control modalities:
- Surgery
- Radiation therapy
- Energy ablation
- Embolization

If primary in place, consider cytoreductive nephrectomy, after appropriate multidisciplinary discussion

Yes

- Resect metastasis
- If primary in place, consider cytoreductive nephrectomy, after appropriate multidisciplinary discussion

Surgically NED?

Yes

- Discuss adjuvant therapy[1] **or**
- Surveillance

No

Refer to systemic regimens on Pages 5-6

NED = no evidence of disease

[1] For stage M1 with NED after nephrectomy or resection of metastatic lesions, consider clinical trial or adjuvant pembrolizumab for up to a year

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Renal Cell Carcinoma

Note: Consider Clinical Trials as treatment options for eligible patients.

PATHOLOGY

Clear cell

SYSTEMIC TREATMENT[1]

- Frontline agents: Favorable risk[2]
  - Preferred regimens
    - Axitinib plus pembrolizumab
    - Cabozantinib plus nivolumab
    - Lenvatinib plus pembrolizumab
  - Other recommended regimens
    - Axitinib plus avelumab
    - Cabozantinib
    - Ipilimumab plus nivolumab
    - Pazopanib
    - Sunitinib
  - Useful in certain circumstances
    - Active surveillance
    - Axitinib
    - High-dose interleukin-2

- Frontline agents: Intermediate or poor risk
  - Preferred regimens
    - Axitinib plus pembrolizumab
    - Cabozantinib plus nivolumab
    - Ipilimumab plus nivolumab
    - Lenvatinib plus pembrolizumab
    - Cabozantinib
  - Other recommended regimens
    - Axitinib plus avelumab
    - Pazopanib
    - Sunitinib
  - Useful in certain circumstances
    - Axitinib
    - High-dose interleukin-2
    - Temsirolimus

- Subsequent therapy agents:
  - Preferred regimens
    - Cabozantinib
    - Lenvatinib plus everolimus
    - Nivolumab
  - Other recommended regimens
    - Axitinib
    - Axitinib plus pembrolizumab
    - Cabozantinib plus nivolumab
    - Ipilimumab plus nivolumab
    - Lenvatinib plus pembrolizumab
    - Pazopanib
    - Sunitinib
    - Tivozanib (≥ 2 prior systemic therapies)
    - Axitinib plus avelumab
    - Previously unused frontline agent
  - Useful in certain circumstances
    - Everolimus
    - Bevacizumab
    - High-dose interleukin-2
    - Sorafenib
    - Temsirolimus
    - Belzutifan

Prolonged period of stabilization and/or regression of lesions?

Yes
- Consider surgical consolidation **or**
- Observation **or**
- Change therapy

No
- Change therapy
- Discuss GCC with patient or if clinically indicated, with Patient Representative[3]

[1] See Appendix A for drug dosing and schedule

[2] International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria:
- Good risk: meets none of the features below
- Intermediate risk: meets 1-2 features below
- Poor risk: meets 3 or more features below

Features include:
- Time from diagnosis to treatment < 1 year
- Karnofsky Performance Status < 80%
- Hypercalcemia (total calcium corrected for albumin)
- Anemia
- Neutrophilia
- Thrombocytosis

[3] GCC should be initiated by the Primary Oncologist. If Primary Oncologist is unavailable, Primary Team/Attending Physician to initiate GCC discussion and notify Primary Oncologist. Patients, or if clinically indicated, the Patient Representative should be informed of therapeutic and/or palliative options. GCC discussion should be consistent, timely, and re-evaluated as clinically indicated. The Advance Care Planning (ACP) note should be used to document GCC discussion. Refer to GCC home page (for internal use only).

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Renal Cell Carcinoma

Note: Consider Clinical Trials as treatment options for eligible patients.

PATHOLOGY

Non-clear cell (papillary, chromophobe, medullary, translocation carcinoma, collecting duct)

SYSTEMIC TREATMENT[1]

- Preferred:
  - Clinical trial
  - Cabozantinib
  - Sunitinib
- Other recommended regimens:
  - Nivolumab
  - Pembrolizumab
  - Lenvatinib plus everolimus
  - Nivolumab plus cabozantinib
- Useful in certain circumstances:
  - Axitinib
  - Bevacizumab
  - Erlotinib
  - Everolimus
  - Pazopanib
  - Temsirolimus
  - Bevacizumab plus erlotinib (HLRCC related RCC and/or papillary RCC)
  - Bevacizumab plus everolimus
  - Nivolumab plus ipilimumab
  - Carboplatin plus paclitaxel or gemcitabine plus doxorubicin (renal medullary carcinoma)
  - Consider empiric individualized therapy with available agents

Response?

Yes → Continue treatment to maximum response → Consider surgical consolidation **or** Observation **or** Change therapy

No → Change therapy; Discuss GCC with patient or if clinically indicated, with Patient Representative[2]

HLRCC = hereditary leiomyomatosis and renal cell cancer

[1] See Appendix A for drug dosing and schedule

[2] GCC should be initiated by the Primary Oncologist. If Primary Oncologist is unavailable, Primary Team/Attending Physician to initiate GCC discussion and notify Primary Oncologist. Patients, or if clinically indicated, the Patient Representative should be informed of therapeutic and/or palliative options. GCC discussion should be consistent, timely, and re-evaluated as clinically indicated. The Advance Care Planning (ACP) note should be used to document GCC discussion. Refer to GCC home page (for internal use only).

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Renal Cell Carcinoma

Note: Consider Clinical Trials as treatment options for eligible patients.

EVALUATION

- Chest x-ray or CT chest
- CT abdomen and optional CT pelvis
- MRI abdomen
- CBC with differential and CMP
- MRI/CT brain if clinically indicated
- Central nervous system imaging if clinically indicated

SUMMARY BY STAGE

Clinical Stage I (T1a/T1b, ≤ 7 cm)

Good surgical candidate?

- **Yes** → Consider biopsy if atypical radiographic findings
  - Partial nephrectomy (if anatomically feasible)
  - Radical nephrectomy
  - Energy ablation
  - Active surveillance
- **No** → Consider biopsy
  - Energy ablation
  - Active surveillance

Clinical Stage II (> 7 cm)

Good surgical candidate?

- **Yes** → Consider biopsy if atypical radiographic findings
  - Partial nephrectomy (if anatomically feasible)
  - Radical nephrectomy
  - → Discuss adjuvant therapy[1] **or**
  - → Surveillance
- **No** → Consider biopsy
  - Active surveillance
  - Embolization

Clinical Stage III (T3a/T3b/N+)

Good surgical candidate?

- **Yes** → Consider biopsy if atypical radiographic findings
  - Radical nephrectomy
  - Partial nephrectomy (optional)
  - → Discuss adjuvant therapy[2] **or**
  - → Surveillance
- **No** → Consider biopsy
  - Systemic therapy
  - Active surveillance
  - Embolization

Clinical Stage IV (M+)

Good surgical candidate?

- **Yes** → Medical oncology consult
  - Consider cytoreductive nephrectomy, after appropriate multidisciplinary discussion (and resection of single metastasis if possible)
  - → Systemic therapy (see Pages 5-6)
- **No**
  - Consider embolization to control primary if symptomatic
  - → Systemic therapy (see Pages 5-6)

[1] For stage II clear cell carcinoma, consider clinical trial or adjuvant pembrolizumab (grade 4 tumors with clear cell histology with or without sarcomatoid features) for up to a year

[2] For stage III clear cell carcinoma, consider clinical trial or adjuvant pembrolizumab (preferred) or sunitinib for up to a year

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SURVEILLANCE

Risk Classification

If final microscopic surgical margins are positive for cancer, the risk category should be considered at least one level higher, and increased clinical vigilance should be exercised

Low Risk (LR): pT1 and Grade 1/2
Intermediate Risk (IR): pT1 and Grade 3/4, or pT2 any Grade
High Risk (HR): pT3 any Grade
Very High Risk (VHR): pT4 or pN1, or sarcomatoid/rhabdoid dedifferentiation, or macroscopic positive margin

Recommended follow-up schedule after surgery for renal cancer (in months)[1]

Risk	3	6	9	12	18	24	30	36	48	60	72-84	96-120
LR	-	-	-	X	-	X	-	-	X	X	X	X
IR	-	X	-	X	-	X	-	X	X	X	X	X
HR	-	X	-	X	X	X	X	X	X	X	X	X
VHR	X	X	X	X	X	X	X	X	X	X	X	X

[1] Follow-up timeline is approximate and allows flexibility to accommodate reasonable patient, caregiver, and institutional needs. Each follow-up visit should include relevant history, physical examination, laboratory testing, and abdominal and chest imaging. Overall, 30% of renal cancer recurrences after surgery are diagnosed beyond 60 months. Informed/shared decision-making should guide surveillance decisions beyond 60 months.

APPENDIX A: Drug Dosing

Drug	Dose and Schedule
Pembrolizumab	200 mg IV every 3 weeks or 400 mg IV every 6 weeks
Axitinib plus pembrolizumab	• Axitinib 5 mg PO twice daily • Pembrolizumab 200 mg IV every 3 weeks or 400 mg IV every 6 weeks
Cabozantinib plus nivolumab	• Cabozantinib 40 mg PO daily • Nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks
Lenvatinib plus pembrolizumab	• Lenvatinib 20 mg PO daily • Pembrolizumab 200 mg IV every 3 weeks or 400 mg IV every 6 weeks
Ipilimumab plus Nivolumab	• Ipilimumab 1 mg/kg IV every 3 weeks for 4 doses • Nivolumab 3 mg/kg (maximum dose 240 mg) IV every 3 weeks for 4 doses, then 6 mg/kg (maximum dose 480 mg) IV every 4 weeks
Cabozantinib	60 mg PO daily
Lenvatinib plus everolimus	• Lenvatinib 18 mg PO daily • Everolimus 5 mg PO daily
Nivolumab	6 mg/kg (maximum dose 480 mg) IV every 4 weeks or 3 mg/kg (maximum dose 240 mg) IV every 2 weeks
Axitinib	5 mg PO twice daily
Pazopanib	800 mg PO daily
Sunitinib	50 mg PO daily for 4 weeks on/2 weeks off **or** 2 weeks on/1 week off
Axitinib plus avelumab	• Axitinib 5 mg PO twice daily • Avelumab 800 mg IV every 2 weeks
Tivozanib	1.34 mg PO daily on days 1 to 21 of a 28-day cycle
Belzutifan	120 mg PO daily
Bevacizumab	10 mg/kg IV every 2 weeks (or 15 mg/kg IV every 3 weeks)
Everolimus	10 mg PO daily
Temsirolimus	25 mg IV weekly
Sorafenib	400 mg PO twice daily

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MD Anderson Institutional Policy #CLN1202 - Advance Care Planning Policy
Advance Care Planning (ACP) Conversation Workflow (ATT1925)

Continued on next page

SUGGESTED READINGS - continued

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DEVELOPMENT CREDITS

This practice algorithm is based on majority expert opinion of the Genitourinary Center providers at the University of Texas MD Anderson Cancer Center. It was developed using a multidisciplinary approach that included input from the following:

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