Note: Consider Clinical Trials as treatment options for eligible patients.
**Urothelial Carcinoma of Bladder and Upper Tract**

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

### STAGE

- **Ta-Unifocal** (low-grade solitary tumor)
  - TUR and surveillance cystoscopy\(^1\) at 3 months and if clear, then 9 months later (at 12 months after initial), and then annually
  - Recurrence?
    - Yes
      - Repeat cystoscopy to assess response (with or without biopsy if indicated) at 3 months
    - No

- **Ta-Multifocal** (low-grade)
  - \*BCG (weekly for 6 weeks) with or without maintenance or Intravesical chemotherapy with maintenance for 1 year or Observation (in selected cases) or Clinical trial

- **Carcinoma In-Situ (CIS)**
  - BCG (weekly for 6 weeks) plus maintenance for 3 years
  - Cystoscopy\(^1\) at 3 and 6 months
  - Persistent carcinoma in-situ at 6 months?
    - Yes
      - Radical cystectomy or Clinical trial or Salvage intravesical therapy or Pembrolizumab\(^2\)
    - No
      - Continue BCG as per SWOG protocol
      - Continue surveillance cystoscopy\(^1\) (every 3 months for 2 years; every 6 months for 2 years; then annually)

---

**TREATMENT AND FOLLOW-UP**

- BCG = Bacillus Calmette-Guerin therapy
- SWOG = Southwest Oncology Group

\(^1\) Cystoscopy combined with either cytology or fluorescence in situ hybridization (FISH) cytology as indicated. In selected patients, fluorescent cystoscopy should be considered.

\(^2\) Pembrolizumab is indicated for the treatment of patients with BCG–unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.
Urothelial Carcinoma of Bladder and Upper Tract

STAGE

High-grade (HG) Ta or T1-Unifocal

Muscle in pathology specimen?

Yes

No

High risk T1

Consider repeating resection in 4-6 weeks, especially with T1

T1: re-biopsy to exclude T2

T1, HG: consider re-biopsy

BCG (weekly for 6 weeks) plus maintenance for 3 years

Cystoscopy

Consider repeat biopsy to assess response at 3 months (if positive cystoscopy or no initial TUR)

Residual disease?

Yes

No

Cystoscopy

Consider early cystectomy

Patient accepts surgery?

Yes

Cystectomy

Upstaged at surgery?

Yes

pT3a

Observation

No

pT3b

N+, margins positive or prostatic stromal invasion pT4a

Observation

No

Yes

pT3a

Observation

Consider adjuvant cisplatin or ifosfamide-based chemotherapy (see Page 9)

See Surveillance on Page 7

Yes

● Radical cystectomy or

● Clinical trial or

● Pembrolizumab

● Continue BCG as per SWOG protocol

● Continue surveillance cystoscopy2 (every 3 months for 2 years; every 6 months for 2 years; then annually)

No

N+ or margins positive or prostatic stromal invasion pT4a

Observation

Department of Clinical Effectiveness

Approved by The Executive Committee of the Medical Staff on 07/21/2020

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

TREATMENT AND FOLLOW-UP

BCG = Bacillus Calmette-Guerin therapy

SWOG = Southwest Oncology Group

1 Pembrolizumab is indicated for the treatment of patients with BCG-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy

2 Cystoscopy combined with either cytology or fluorescence in situ hybridization (FISH) cytology as indicated. In selected patients, fluorescent cystoscopy should be considered.

3 T1 multifocal, variant histology with concurrent carcinoma in situ (CIS), lymphovascular invasion (LVI) and/or resectable tumor 3 cm or greater with poor prognosticator or too large to resect completely

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Page 3 of 18
Urothelial Carcinoma of Bladder and Upper Tract

TREATMENT AND FOLLOW-UP

STAGE

- EUA
- CT chest, abdomen, and pelvis
- CT chest if positive chest x-ray or clinical suspicion for metastasis
- Bone scan if elevated alkaline phosphatase or bone pain

T2/3a, N0, M0

- Presence of poor risk factors1?

T2-4 (muscle invasion)

- Neoadjuvant chemotherapy2
- Clinical trial

Patient accepts surgery?

T3b/4a, N0, M0

- Neoadjuvant chemotherapy2
- Clinical trial

Consider metastatic chemotherapy clinical trial if available

T4b, N0, M0

Assess response by:
- Cystoscopy
- EUA
- Imaging

Resectable?

Yes

Radical cystectomy

Yes

Salvage therapy

Consider cystectomy if surgically resectable

No

Cystectomy

Upstaged at surgery?

Yes

Yes

Bladder sparing treatment
- Chemoradiation or
- Clinical trial

No

Observation

No

Observation

No

Additional chemotherapy

Yes

Radical cystectomy

See Surveillance on Page 7

Yes

Patient accepts surgery?

No

T2/3a

T3b/4a

pT3a

pT3b

N+, margins positive or prostatic stromal invasion pT4a

- Adjuvant cisplatin or ifosfamide-based chemotherapy (see Page 9) or
- Clinical trial

1 Poor risk factors:
- Lymphovascular invasion
- Inability to assess depth of invasion
- Variant histology such as small cell
- Hydronephrosis
- Tumor involving bladder diverticulum

2 Consider neoadjuvant/adjuvant cisplatin or ifosfamide-based systemic chemotherapy (i.e., DDMVAC, IAG, etc.). Refer to Principles of Systemic Therapy on Page 8

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

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Urothelial Carcinoma of Bladder and Upper Tract

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

**CLINICAL PRESENTATION**

- Positive pelvic nodes or nodes below aortic bifurcation
- Nodes below aortic bifurcation
- Nodes above aortic bifurcation or visceral metastasis
- CT chest, abdomen, and pelvis
- Bone scan

**METASTATIC DISEASE**

- Chemotherapy
  - Consider metastatic clinical trial if available

- CT chest, abdomen, and pelvis
- Bone scan

- Assess response by:
  - Cytoscopy
  - EUA
  - Imaging

- Resectable?

- Non-nodal metastasis
- Yes
- Surgical consolidation trials
- No

- See Surveillance on Page 7

Clinical trial or systemic treatment as per patient’s co-morbid medical conditions:

Front-line systemic treatment or clinical trials:

- Cisplatin eligible:
  - GFR ≥ 50 mL/minute: full dose cisplatin or ifosfamide-based combinations (i.e., DDMVAC, GC, IAG, ITP, GTP)
  - GFR ≥ 40 mL/minute and < 50 mL/minute: modified cisplatin-combinations including DDMVAC with split-dose cisplatin, GC with split-dose, CGI, or TMP

- Cisplatin ineligible:
  - Nephron-sparing combinations: GTA, GCtx, GVinorelbine
  - Pembrolizumab or atezolizumab may be consider for PD-L1 high tumors

Second-line systemic treatment or clinical trials:

- FGFR3 mutation or fusion:
  - Erdafitinib

- Wild type FGFR3:
  - Immune checkpoint inhibition: pembrolizumab, nivolumab, atezolizumab, durvalumab, or avelumab
  - Ineligible for immune checkpoint inhibition: consider alternative chemotherapy regimen from the front-line list of therapies or single agent taxane or move to third-line treatment below

Third-line systemic treatment or clinical trials:

- Enfortumab vedotin (nectin-4 testing is not required)

- Ineligible for third-line treatment: consider alternative chemotherapy regimen from the front-line list of therapies or single agent taxane

DDMVAC = dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin
GC = gemcitabine and cisplatin
IAG = ifosfamide, doxorubicin, and gemcitabine
ITP = ifosfamide, paclitaxel, and cisplatin
GTX = gemcitabine and cyclophosphamide
GVinorelbine = gemcitabine and vinorelbine

1 Consider mutation testing
2 Patients are generally considered surgically resectable if no tumor present in the bladder and near complete response in lymph nodes. If tumor still present on cystoscopy or on biopsy of nodes, consider additional chemotherapy prior to considering surgical consolidation.
3 See Appendix A for standard systemic treatments

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Urothelial Carcinoma of Bladder and Upper Tract

CLINICAL PRESENTATION

Upper tract (renal pelvis or ureter) tumor

- CT urogram
- Cystoscopy
- Ureteroscopy
- Biopsy (forceps or brush) strongly recommended
- Washing adequate only if positive for high grade
- MSI testing

Low risk

- CT urogram
- Cystoscopy
- Ureteroscopy
- Biopsy (forceps or brush) strongly recommended
- Washing adequate only if positive for high grade
- MSI testing

High risk: High grade disease, sessile architecture, cT3 on imaging, or based upon clinical nomograms

Metastatic disease

See Box A on Page 5

TREATMENT AND FOLLOW-UP

Patient suitable for conservative management?

- Yes
- Surgical removal
  - Nephroureterectomy with bladder cuff
  - Occasionally may consider segmental resection
  - Regional node dissection (if high grade or stage)

- No
  - Consider instillation of mitomycin gel (JelmytoTM) or Holmium laser ablation or Consider adjuvant instillation of BCG (2-3 weeks later) or intraluminal chemotherapy

Greater than or equal to pT3, LVI+, or N+, or based on expected recurrence risk per nomogram?

- Yes
- Consider adjuvant chemotherapy or clinical trials

- No
- Observation

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

MSI = microsatellite instability

1 See Appendix B and Appendix C for clinical risk nomograms
2 Conservative management is based on individual patient status and clinical findings; elective indications ideally meet low-risk European Association of Urology (EAU) criteria: unifocal disease, tumor size <2 cm, low-grade cytology, low-grade ureteroscopic (URS) biopsy, and no invasive aspect on computed tomography urography (CTU)
3 See Appendix D for postoperative nomogram for prediction of relapse-free survival
4 Consider neoadjuvant/adjuvant cisplatin or ifosfamide-based systemic chemotherapy (i.e., DDMVC, IAG, etc.). Refer to Principles of Systemic Therapy on Page 9.
SURVEILLANCE AFTER RADICAL CYSTECTOMY

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<td>x</td>
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<td>x</td>
</tr>
</tbody>
</table>

PE = physical examination

¹After 5 years, follow guidelines every 1-2 years at the discretion of the treating physician

²Patients with adverse pathologic features, e.g. micropapillary disease, presence of lymphovascular invasion (LVI), sacromatoid de-differentiation, or those who have been downstaged after neoadjuvant chemotherapy, may be followed as pT2 patients

³History should include urethral discharge/bloody mucus

⁴Laboratory tests include CBC, electrolytes, BUN, creatinine, and LFTs. Cytology is optional if imaging is routinely obtained.

⁵As clinically indicated

Note: For all patients with urinary diversion, imaging study 6-8 weeks after surgery to confirm patency of anastomosis is at treating surgeon’s discretion. Choices include: loopogram (or cystogram), IVU, or renal ultrasound.

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Urothelial Carcinoma of Bladder and Upper Tract

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BLADDER CANCER TREATMENT PRINCIPLES

PRINCIPLES OF RADIATION THERAPY MANAGEMENT
OF INVASIVE DISEASE
- External beam radiation is rarely appropriate for patients with superficial tumors or carcinoma in situ (CIS). Surgery remains the standard of care.
- Precede radiation by maximal transurethral resection (TUR) of the tumor when safely possible.
- Combining concurrent chemotherapy with radiation is encouraged for added tumor cytotoxicity.
- Simulate and treat patients with the bladder empty.
- Use multiple fields from high-energy linear accelerator beams.
- Treat the whole bladder with 40-55 Gy and then boost bladder tumor to a total dose of 64-66 Gy excluding, if possible, normal areas of bladder from the high-dose volume.

PRINCIPLES OF SYSTEMIC THERAPY
Active agents:
- Two-to-three drug combinations based on cisplatin, docetaxel, paclitaxel, ifosfamide, gemcitabine or MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) are used for treatment of metastatic disease. Adjuvant or neoadjuvant therapy is also considered for patients at high risk of recurrence.
- Patients at increased risk for morbidity from more toxic regimens (e.g., MVAC) may be treated with combinations of lower toxicity profiles. These patients are characterized by more than one of the following:
  - Comorbid conditions
  - High alkaline phosphatase
  - Poor performance status
  - High LDH
  - Liver or bone metastases
  - Poor renal function
- Immunotherapy (pembrolizumab, nivolumab, atezolizumab, durvalumab, or avelumab) has been approved for patients failing frontline chemotherapy. PD-L1 testing is not required.
- Atezolizumab and pembrolizumab are indicated front-line for cisplatin ineligible patients whose tumors are PD-L1 high.
- Erdafitinib has been approved second-line for patients with FGFR3 mutations and fusions.
- Enfortumab vedotin has been approved for third-line setting. Nectin-4 testing is not required.

PRINCIPLES OF SURGICAL MANAGEMENT
TRANURETHRAL RESECTION OF BLADDER TUMOR (TURBT)
- The first step in surgical management of bladder tumors is a complete TUR of the tumor. Muscle must be present in the TUR specimen to appropriately stage the tumor; if no muscle is present in the specimen, re-resection/biopsy of tumor base should be discussed with patient.
- Repeat TUR at 4-6 weeks is to be strongly considered if incomplete initial resection, no muscle in specimen, or T1 stage. It must also be considered if first TURBT does not allow adequate staging or attribution of risk factor for treatment selection or when using bladder-preserving treatment by chemotherapy and/or radiation therapy.
- In cases of positive cytology with no evidence of tumor, patient should undergo multiple biopsies of the bladder mucosa (if visibly abnormal with or without use of fluorescent cystoscopy) as well as prostate urethral biopsies and evaluation of upper tracts.

RADICAL CYSTECTOMY
- Radical cystectomy should include bilateral pelvic node resection with goal of at least 10 nodes removed.
- Nerve sparing and type of diversion selected depends on many factors, several of which are patient specific.

PRINCIPLES OF INTRAVESICAL TREATMENT
- Immunotherapy
  - Bacillus Calmette-Guerin (BCG) immunotherapy is the most effective treatment for non muscle invasive bladder cancer.
  - It is ideal to wait 14-21 days after TURBT (no gross hematuria).
  - BCG induction (6 weekly treatments) should be followed by maintenance therapy (weekly for 3 weeks at months 3 and 6, and then every 6 months for a total of 3 years).
  - Dose reduction of BCG is preferable to shorter duration of maintenance.
  - If patient fails 2 courses of BCG, strongly consider radical cystectomy (or clinical trial).
- Chemotherapy
  - Peri-operative intravesical chemotherapy is most effective when given right after TUR (ideally within 6 hours).
  - Induction and maintenance chemotherapy in selected patients if indicated.
  - Agents include gemcitabine and mitomycin.
- Salvage therapy after BCG is preferably with combination chemotherapy (i.e., gemcitabine and docetaxel).

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Approved by The Executive Committee of the Medical Staff on 07/21/2020

Department of Clinical Effectiveness V9
## APPENDIX A: Standard Systemic Treatments

### Chemotherapy Regimens:

- **Dose-dense MVAC (DDMVAC):**
  - Methotrexate 30 mg/m² IV and
  - Vinblastine 3 mg/m² IV and
  - Doxorubicin 30 mg/m² IV and
  - Cisplatin 70 mg/m² IV
    - Cisplatin followed with D5 1/4 NS IV plus mannitol 40 g/L with appropriate potassium and magnesium, typically for 3 liters

  This regimen is repeated every 2 weeks with growth factor support

- **Gemcitabine, cisplatin (GC):**
  - Gemcitabine 900 mg/m² IV over 90 minutes on Day 1 and Day 8 and
  - Cisplatin 70 mg/m² IV on Day 1
    - Cisplatin followed with D5-1/4 NS IV plus mannitol 40 g/L with appropriate potassium and magnesium, typically for 3 liters

  This regimen is repeated every 3 weeks with growth factor support as needed

- **Gemcitabine, Paclitaxel, Doxorubicin (GTA):**
  - Doxorubicin 30 mg/m² IV and
  - Paclitaxel 135 mg/m² IV and
  - Gemcitabine 900 mg/m² IV

  This regimen is repeated every 2 weeks with growth factor support

- **Ifosfamide, Doxorubicin, Gemcitabine (IAG):**
  - Ifosfamide 1500 mg/m² IV plus Mesna 300 mg/m² IV on day 1 through day 4 and
    - Mesna given at hours 0, 4, and 8 (with respect to Ifosfamide’s start time)
  - Doxorubicin 45 mg/m² IV on day 3 only and
  - Gemcitabine 150 mg/m² IV on day 2 and day 4

  This regimen is repeated every 3 weeks with growth factor support

- **Cisplatin, Gemcitabine, Ifosfamide (CGI):**
  - Gemcitabine 900 mg/m² IV on day 1 and
  - Ifosfamide 1000 mg/m² IV on day 1 and
  - Cisplatin 50 mg/m² IV on day 1
    - Cisplatin followed with 1/4 NS IV plus mannitol 40 g/L, typically for 3 liters

  This regimen is repeated every 2 weeks with growth factor support

### Biotherapy and Targeted Therapy Regimens:

- **Atezolizumab 1.200 mg IV every 3 weeks**
- **Avelumab 800 mg IV every 2 weeks**
- **Durvalumab 10 mg/kg IV every 2 weeks**
- **Enfortumab 1.25 mg/kg IV on days 1, 8, and 15 of every 4 weeks**
- **Erdafitinib 8 mg PO daily**
  - May titrate up to 9 mg PO daily if phosphorous level on Day 15 is ≤ 5.5 mg/dL
- **Nivolumab 240 mg IV every 2 weeks or 480 mg IV every 4 weeks**
- **Pembrolizumab 200 mg IV every 3 weeks or 400 mg IV every 6 weeks**
Urothelial Carcinoma of Bladder and Upper Tract

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APPENDIX B: Clinical Risk Nomograms

Preoperative relapse-free probability following radical nephroureterectomy for high grade upper tract urothelial carcinoma

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<td>0.6</td>
<td>0.5</td>
<td>0.4</td>
<td>0.3</td>
<td>0.2</td>
<td>0.1</td>
<td>0.03</td>
</tr>
<tr>
<td>5-year Relapse-Free Probability</td>
<td>0.93</td>
<td>0.9</td>
<td>0.8</td>
<td>0.7</td>
<td>0.6</td>
<td>0.5</td>
<td>0.4</td>
<td>0.3</td>
<td>0.2</td>
<td>0.1</td>
<td>0.05</td>
</tr>
</tbody>
</table>

* Based on imaging studies

Urothelial Carcinoma of Bladder and Upper Tract

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APPENDIX C: Clinical Risk Nomograms

Preoperative probability of non-organ confined (pT3-4, N+) upper tract urothelial carcinoma, low or high grade

* Peripelvic fat, parenchymal invasion (renal tumor) or periureteral fat invasion (ureteral tumor) or other infiltrative component on imaging


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APPENDIX D: Postoperative nomogram for prediction of relapse-free survival

Non-muscle Invasive Bladder Cancer


Muscle Invasive Bladder Cancer


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SUGGESTED READINGS

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SUGGESTED READINGS – continued

Muscle Invasive Bladder Cancer- continued


Chemotherapy


Continued on next page
SUGGESTED READINGS – continued

Chemotherapy - continued


Immunotherapy


Targeted Therapy


Continued on next page
SUGGESTED READINGS – continued

Rare Bladder Tumors


Small Cell


Plasmacytoid

Micropapillary


Continued on next page
Urothelial Carcinoma of Bladder and Upper Tract

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SUGGESTED READINGS – continued

Upper Tract


Urachal


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