



# NCG GUIDELINES- 2019 Urological Malignancies Management Guidelines

### **Categories of the guidelines**

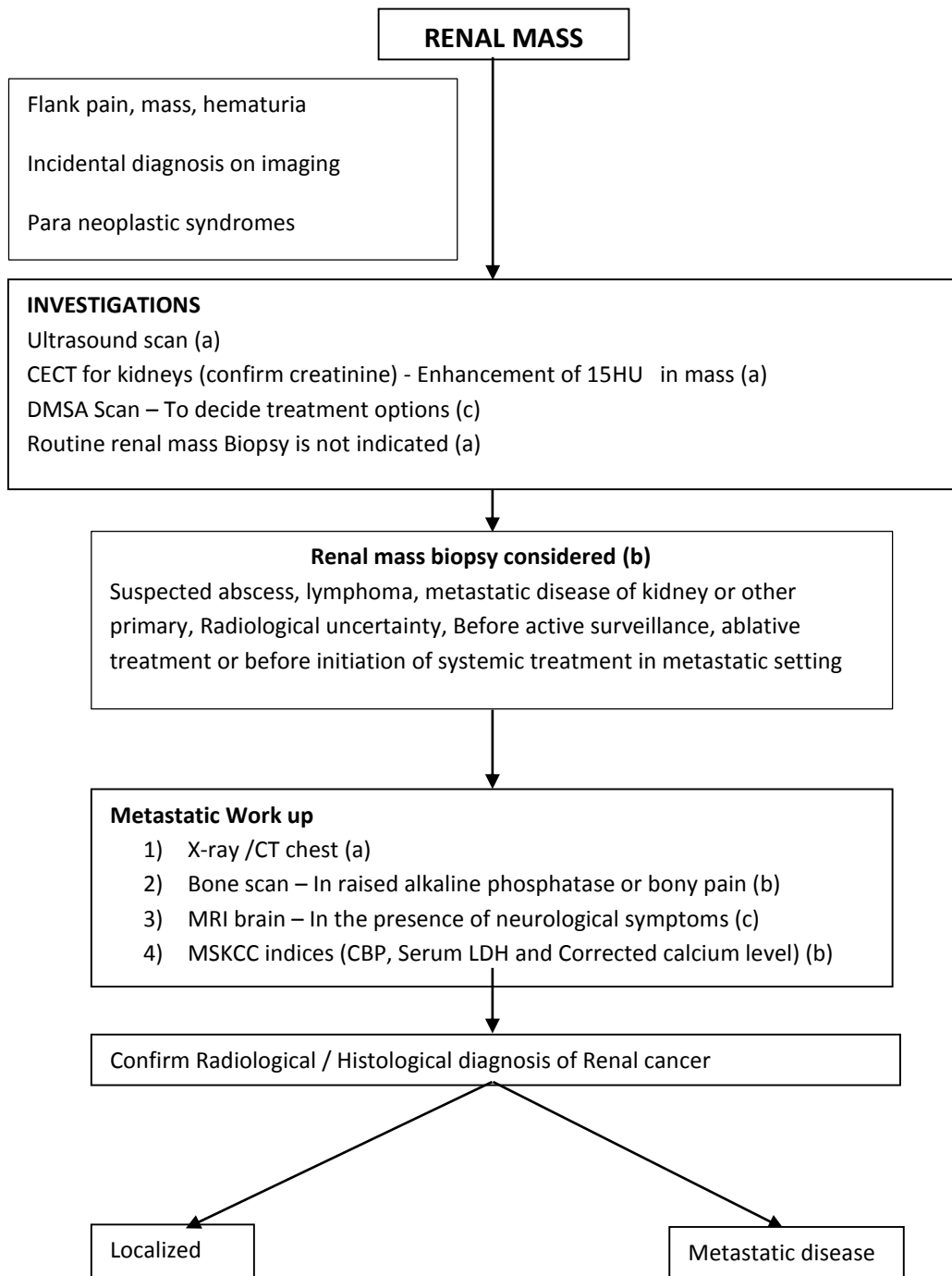
- a) Essential
- b) Optimal
- c) Optional

*\*Herewith essential will be referred as (a), optimal as (b) and optional as (c)*

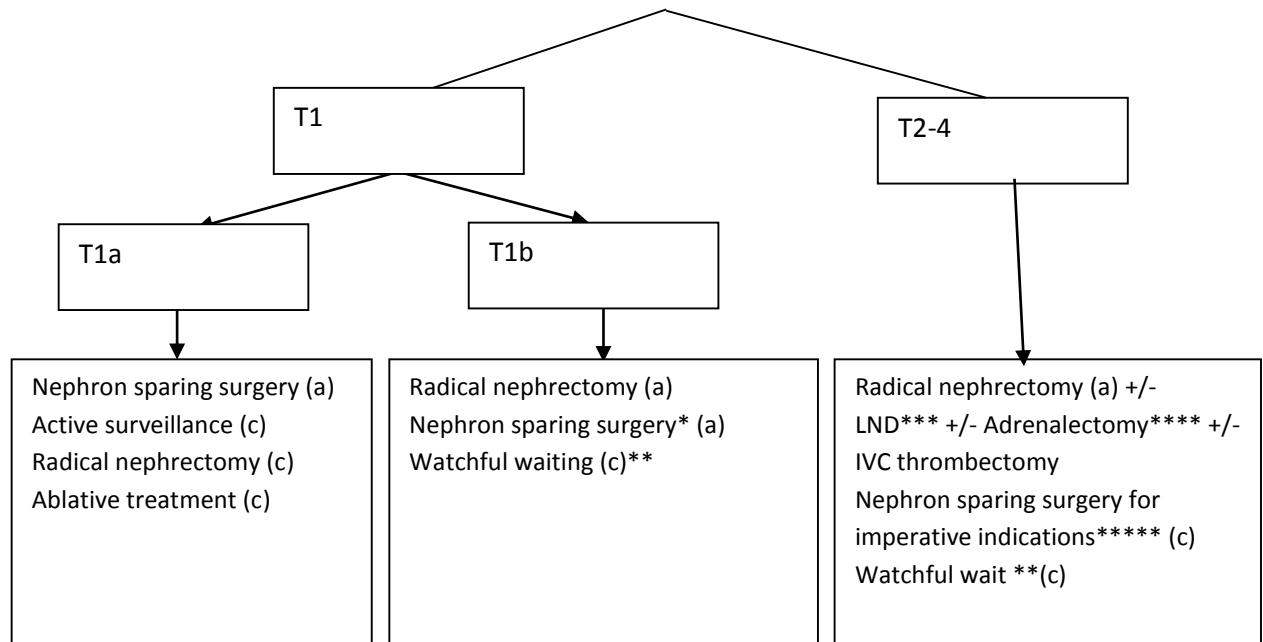
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**INVESTIGATIONAL PATHWAY FOR RENAL CELL CARCINOMA**



**Treatment pathway for localized disease**



Surgical approach - Open/ Laparoscopic / Robotic-Individual surgeon discretion

\*Nephron sparing surgery when technically feasible

\*\*Watchful waiting: In patient with poor Performance status, significant comorbidity, asymptomatic, poor renal function

\*\*\*LND – Lymph Node Dissection (18,19)

In patients of cT3-4, cN+, Intraoperative N+

Rt side extent – Hilar, precaval, retrocaval, interaortocaval

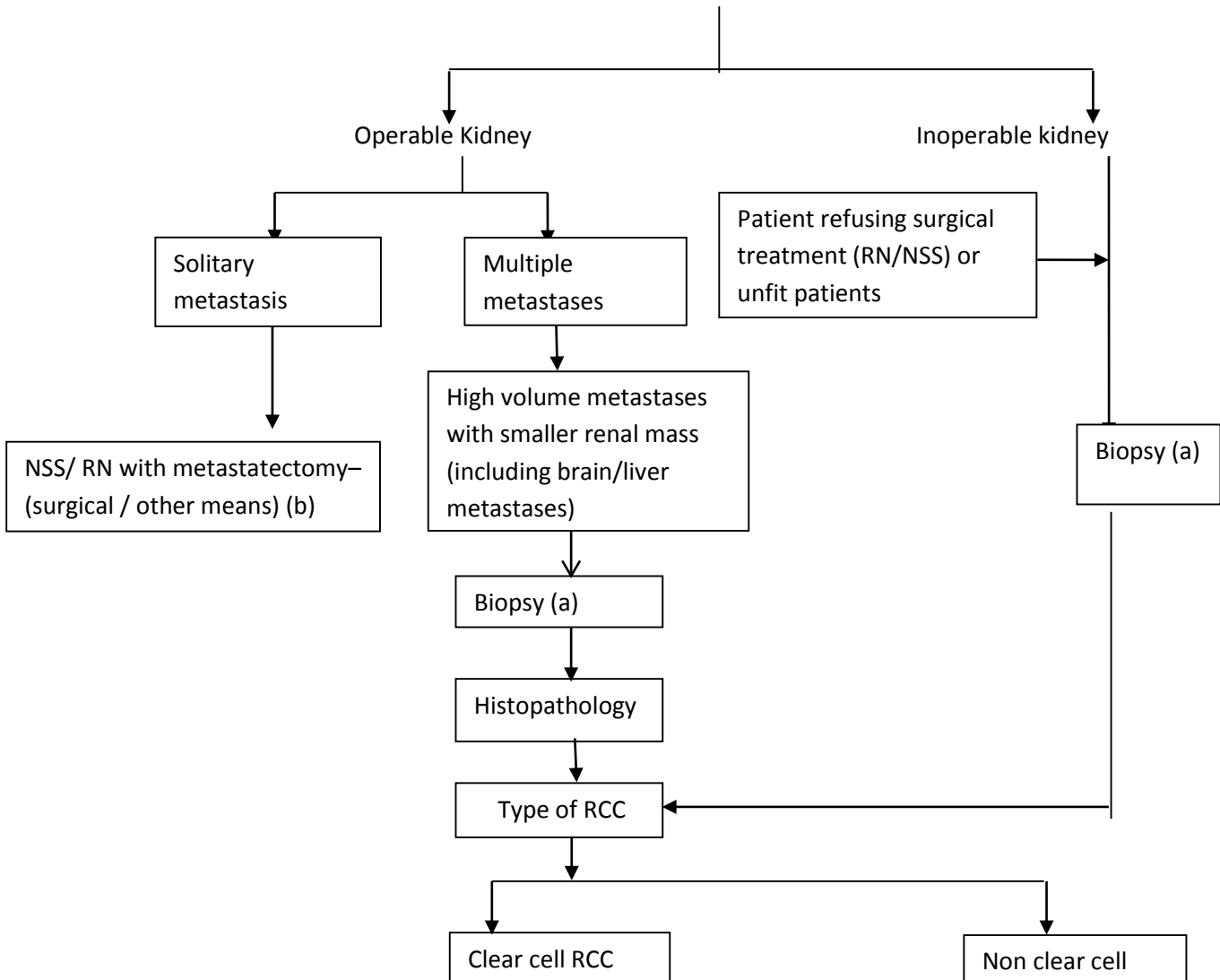
Lt side extent – hilar, paraaortic, retroaortic, interaortocaval

\*\*\*\*Adrenalectomy – only if contiguous involvement

CT shows on abnormal adrenal gland, intra-operative findings suggest intra-adrenal metastatic spread or large upper pole tumour

\*\*\*\*\* Nephron sparing surgery when technically feasible in young patients who have bilateral disease, borderline renal function, multiple tumours.

**Treatment pathway for metastatic disease**

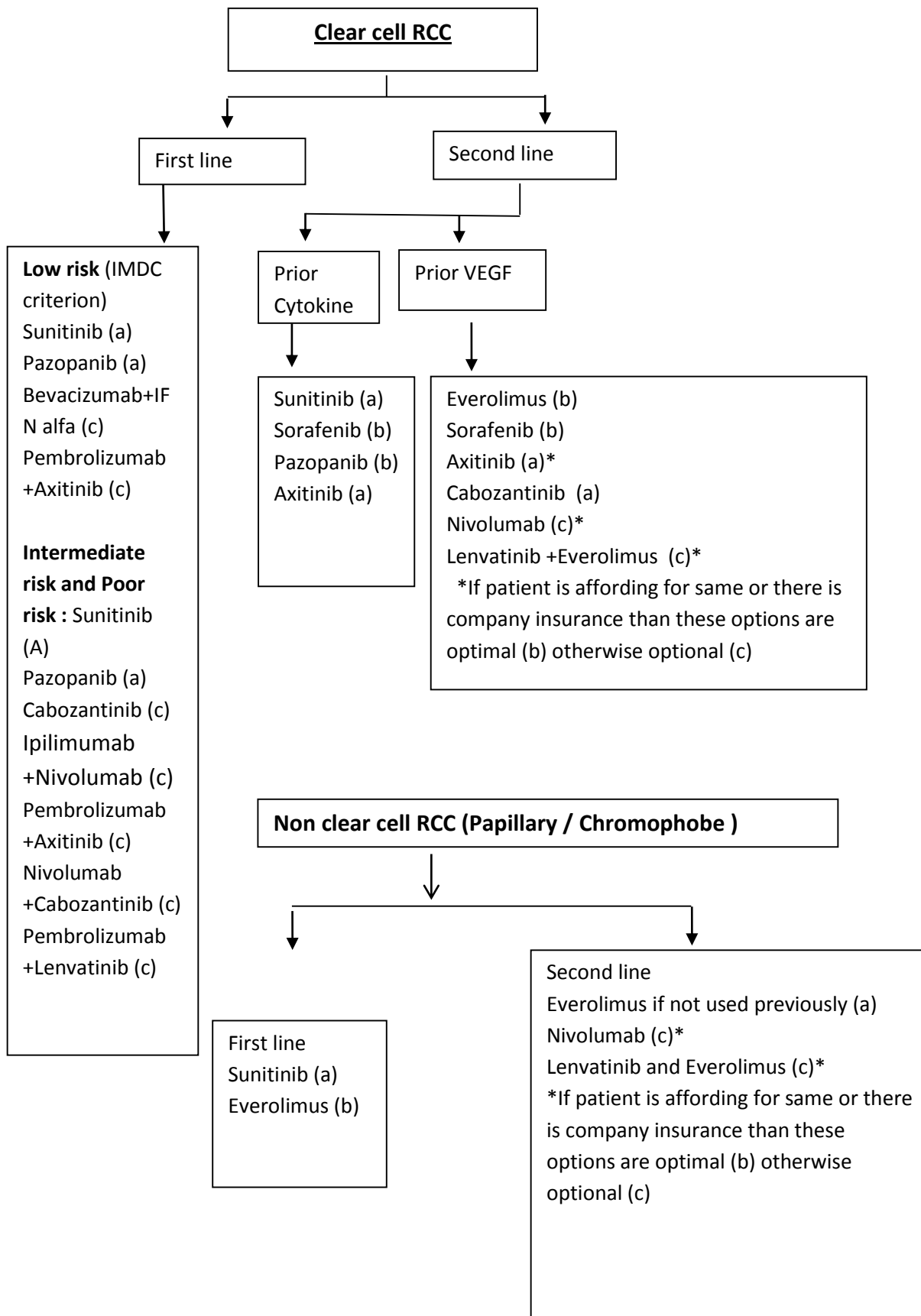


Surgery of primary renal mass in presence metastatic disease if planned for TKIs: As per MSKCC risk criteria: (b)

GOOD RISK: Primary renal mass surgery to be considered

INTERMEDIATE RISK: may or may not Individualized approach

POOR RISK: Primary renal mass surgery not to be done



Proposed surveillance schedule following treatment for RCC, taking into account patient risk profile and treatment efficacy

Risk profile	Treatment	Surveillance						
		6 mo	1yr	2yr	3yr	4yr	5yr	>5yr
Low	RN/PN only	US	CT	US	CT	US	CT	Discharge
Intermediate	RN/PN/cryo /RFA	CT	CT	CT	US	CT	CT	CT once every 2 years
High	RN/PN/cryo /RFA	CT	CT	CT	CT	CT	CT	CT once every 2 years

- Blood test must include sr creatinine, blood urea nitrogen, electrolytes, sr calcium, alkaline phosphatase, and a liver function panel

Tab Sunitinib 50 mg OD for 2 weeks and then one week gap and then again 50 mg OD for 2 weeks ,this cycle will continue till disease progression

Tab Pazopanib 800 mg OD daily till disease progression

Tab Cabozantinib 60 mg OD till disease progression

Inj Nivolumab (3 mg/kg) plus Ipilimumab (1 mg/kg) was given every three weeks for four doses, followed by single-agent nivolumab (3 mg/kg or a flat dose of 240 mg till progression or every two weeks for up to two years

Inj Pembrolizumab 200 mg every 3 weekly with Tab Axitinib 5 mg BD for two year

Tab Everolimus 10 mg OD till disease progression

Tab Lenvatinib 18 mg +Tab Everolimus 5 mg OD till disease progression

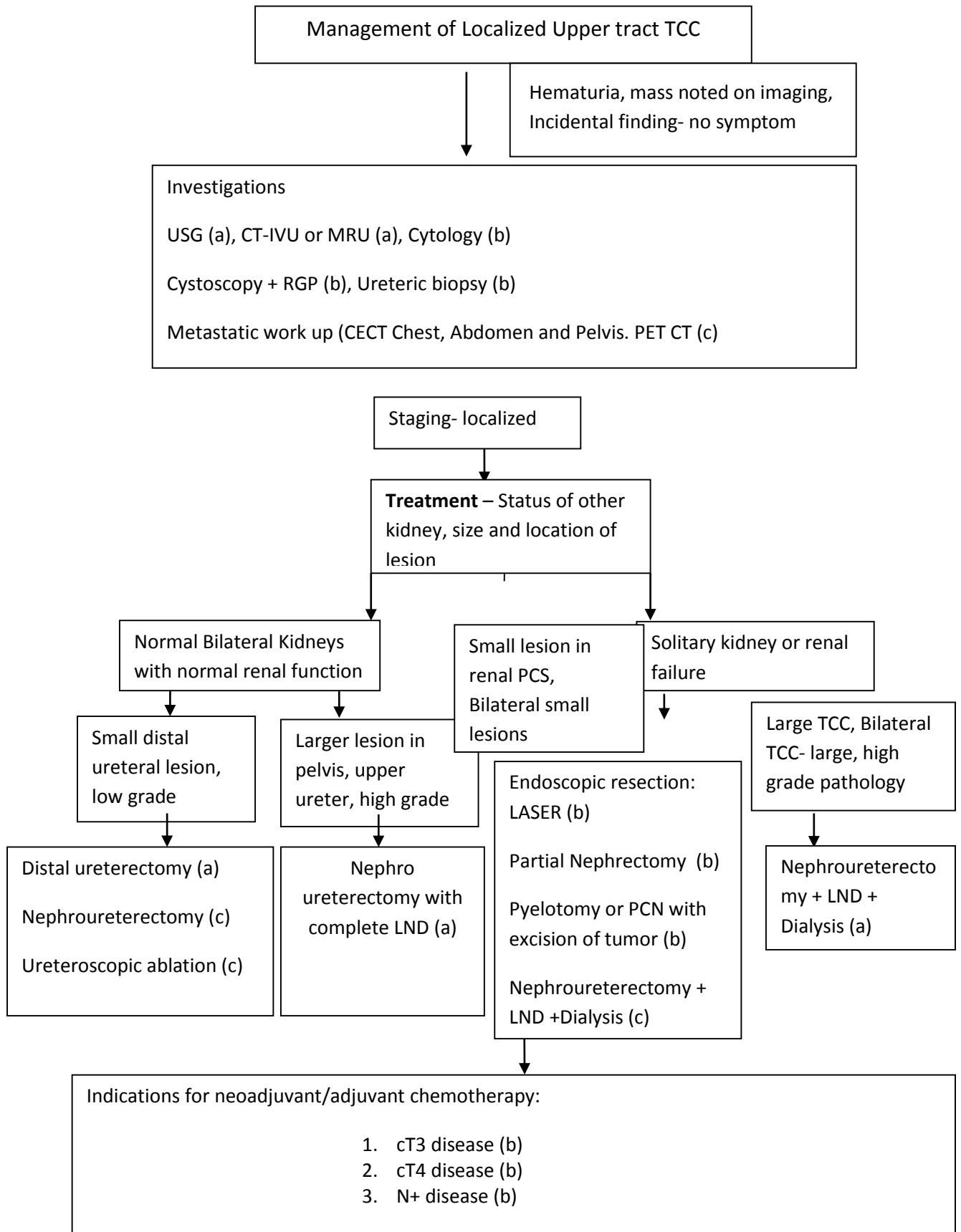
Tab Axitinib 5 mg BD till disease progression

Tab Sorafinib 400 mg BD till disease progression

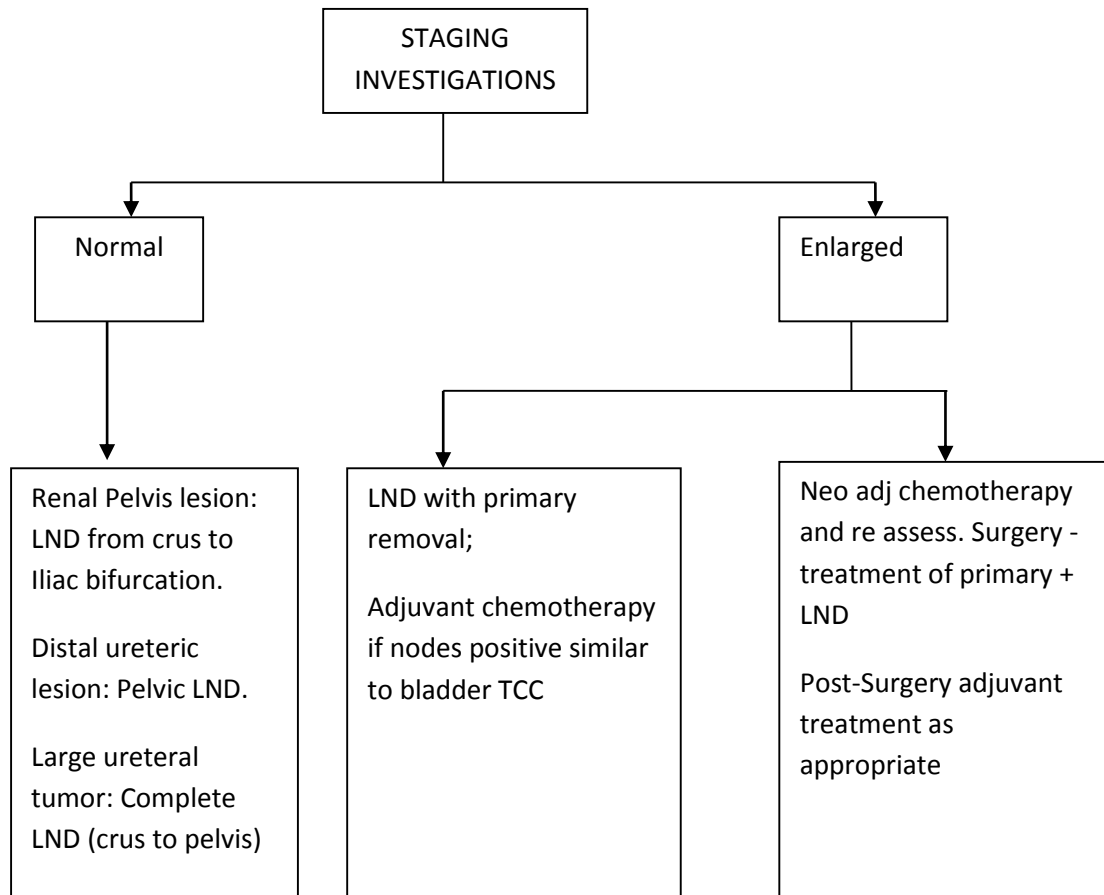
Inj Nivolumab 240 mg IV every 2 weekly till disease progression



**UPPER TRACT UROTHELIAL CARCINOMA**



**MANAGEMENT OF METASTATIC DISEASE IN UPPER TRACT  
 UROTHELIAL CARCINOMA**



Metastatic disease  
 (Managed in same line as metastatic urinary bladder cancer)

**Neoadjuvant chemotherapy in carcinoma of urinary tract (NACT) :**

Inj Gemcitabine (1000 mg/m<sup>2</sup> on days 1, 8, 15) plus cisplatin (70 mg/m<sup>2</sup> on day 2), repeated every 28 days for a maximum of 4 cycles .

Or

Inj Gemcitabine (1200/1000 mg/m<sup>2</sup> on days 1 and 8) and cisplatin (75 mg/m<sup>2</sup> on day 2), repeated every 21 days for a median of 4 cycles

Or

Inj Gemcitabine (1000 mg/m<sup>2</sup> on days 1 and 8) and cisplatin (35 mg/m<sup>2</sup> on day 1 and day 8 ) , repeated every 21 days for a median of 4 cycles

**Dose-dense MVAC :**

Inj Methotrexate (30 mg/m<sup>2</sup> on day 1), Inj vinblastine (3 mg/m<sup>2</sup> on day 2), Inj doxorubicin (30 mg/m<sup>2</sup> on day 2), and Inj cisplatin (70 mg/m<sup>2</sup> on day 2) with granulocyte-colony stimulating factor (G-CSF) support, repeated every 14 days for six cycles

**Adjuvant chemotherapy:**

Inj Gemcitabine (1000 mg/m<sup>2</sup> on days 1, 8, 15) plus cisplatin (70 mg/m<sup>2</sup> on day 2), repeated every 28 days for a maximum of 4 cycles .

Or

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Or

Inj Gemcitabine (1000 mg/m<sup>2</sup> on days 1 and 8) and cisplatin (35 mg/m<sup>2</sup> on day 1 and day 8 ) , repeated every 21 days for a median of 4 cycles

Or

Inj Carboplatin AUC 5 on Day 1 and Inj Gemcitabine 1000 mg /m<sup>2</sup> on day 1 and day 8, cycle every 3 weekly for maximum 4 cycles

**Treatment of metastatic urothelial cancer of the urinary tract:**

**Cisplatin eligible:**

Inj Gemcitabine (1000 mg/m<sup>2</sup> on days 1, 8, 15) plus cisplatin (70 mg/m<sup>2</sup> on day 2), repeated every 28 days for a maximum of 6 cycles .

Or

Inj Gemcitabine (1200 mg/m<sup>2</sup> on days 1 and 8) and cisplatin (75 mg/m<sup>2</sup> on day 2), repeated every 21 days for a median of 6 cycles

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Inj Avelumab 800 mg once every 2 weeks until disease progression or unacceptable toxicity as a maintenance therapy in patients who has stable disease, partial response or complete response after 4 to 6 cycles of platinum based chemotherapy

**Cisplatin ineligible:**

Inj Carboplatin AUC 5 on Day 1 and Inj Gemcitabine 1000 mg /m<sup>2</sup> on day 1 and day 8, cycle every 3 weekly for maximum 6 cycles .

Inj Paclitaxel 200 mg/m<sup>2</sup> by 1-hour intravenous (IV) infusion on day 1 and Gemcitabine 1,000 mg/m<sup>2</sup> IV on days 1, 8, and 15; courses were repeated every 21 days for 4 cycles

Inj Pembrolizumab 200 mg once every 3 weekly

Inj Atezolizumab 1,200 mg once every 3 weeks

**Second line therapy:**

Inj Paclitaxel 80 mg/m<sup>2</sup> weekly till disease progression or unacceptable toxicities

Inj Pemetrexed 500 mg /m<sup>2</sup> every 3 weekly till disease progression or unacceptable toxicities

Inj Gemcitabine 1000 mg /m<sup>2</sup> day 1 and day 8 every 3 weekly till disease progression or unacceptable toxicities

Inj Docetaxel 75 mg/m<sup>2</sup> 3 weekly for 6 cycles

Inj Nivolumab 240 mg every 2 weekly till disease progression or unacceptable toxicities

Inj Pembrolizumab 200 mg every 3 weekly till disease progression or unacceptable toxicities

**BLADDER CARCINOMA**

**Investigational pathway for Bladder carcinoma**

**Symptoms:** Visible and non-visible haematuria, passing clots or tissue bits in urine, persistent irritative urinary symptoms

**Imaging**  
USS Abdomen and Pelvis (a)  
Intravenous Urography /CT Urogram (a)  
MR Urogram (b)

**Investigations**  
-CBP and Renal profile (a)  
-Diagnostic Cystoscopy ± biopsy (b)  
- Urine Cytology (c)  
- Advanced vision investigation (Narrow band imaging/  
Fluorescent cystoscopy) (c)

**Investigations when muscle invasive bladder tumour is suspected**  
- CT Chest abdomen and Pelvis with contrast (b)  
FDG PET CT (c)

Examination under anesthesia and Transurethral resection of Bladder tumour.  
TURBT findings should include: Number and size of tumours, relation to ureteric orifices, comment on urethra, Prostate and bladder neck (a).  
Following TURBT for suspected non-muscle invasive bladder tumour patients, one dose of Intravesicle Mitomycin at the dosage of 40mg in 50 ml of saline should be administered for Intravesicle treatment within 24hrs of resection (a)

Non-Metastatic disease

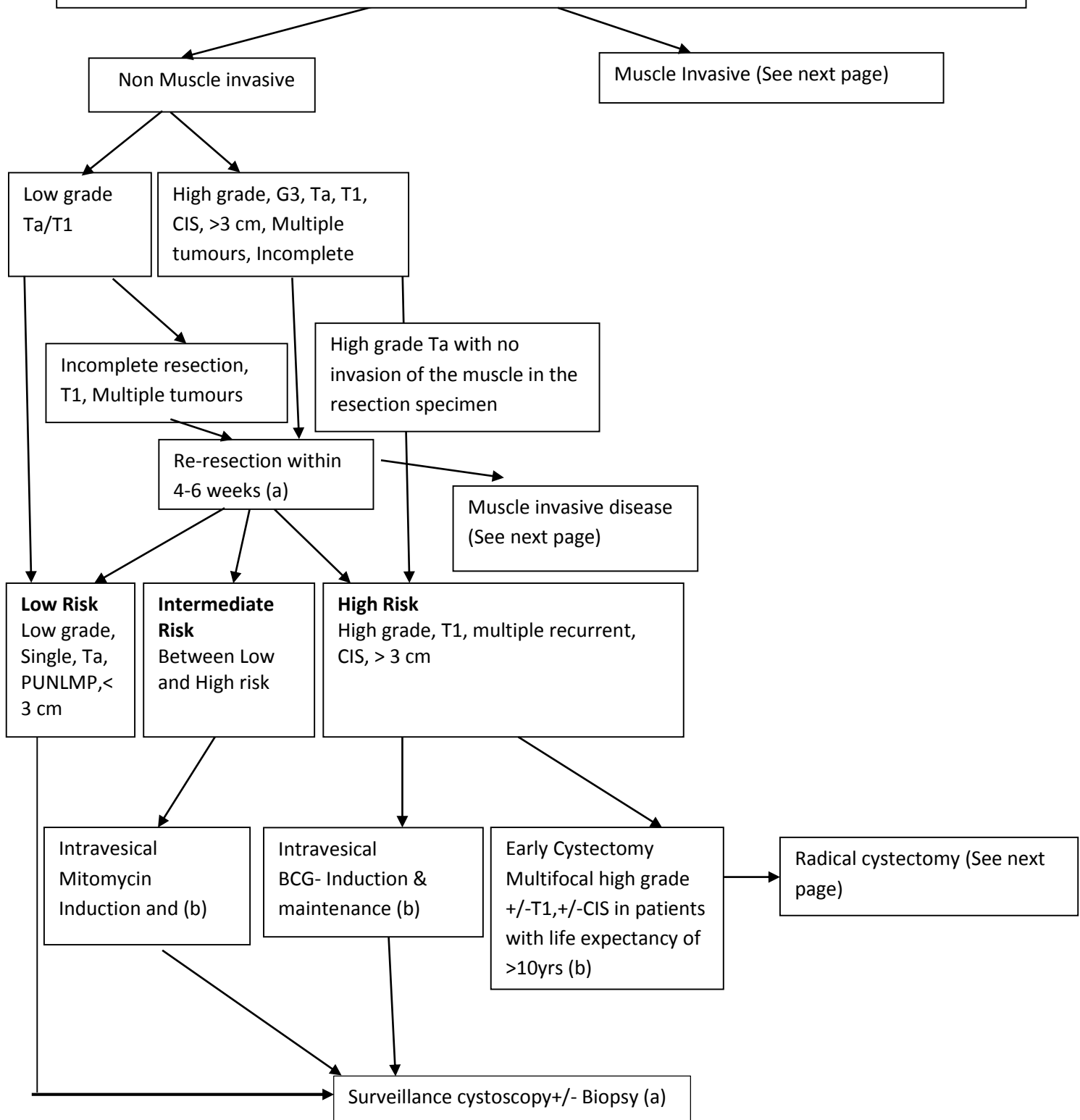
Metastatic disease

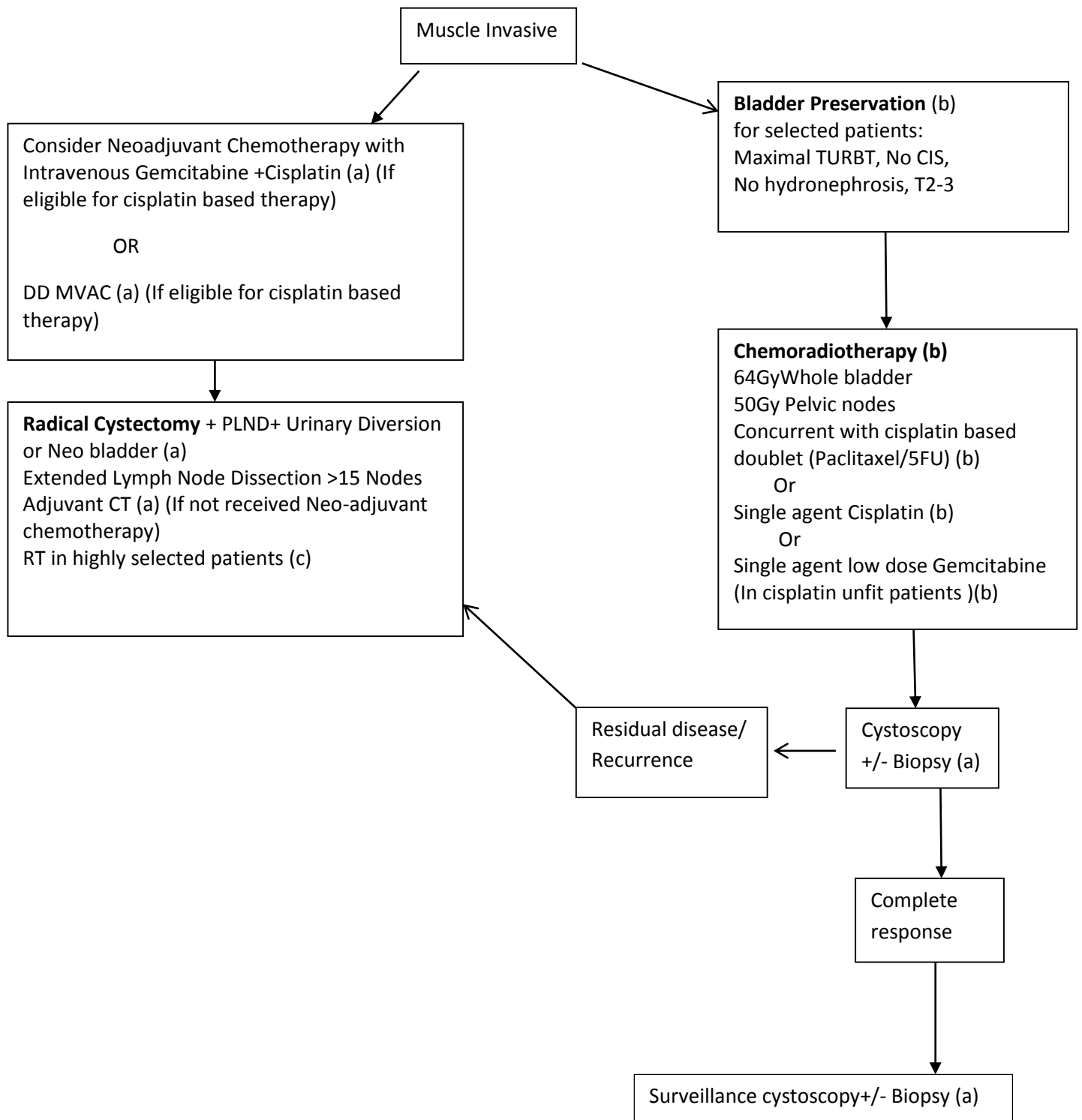
Non-Muscle invasive

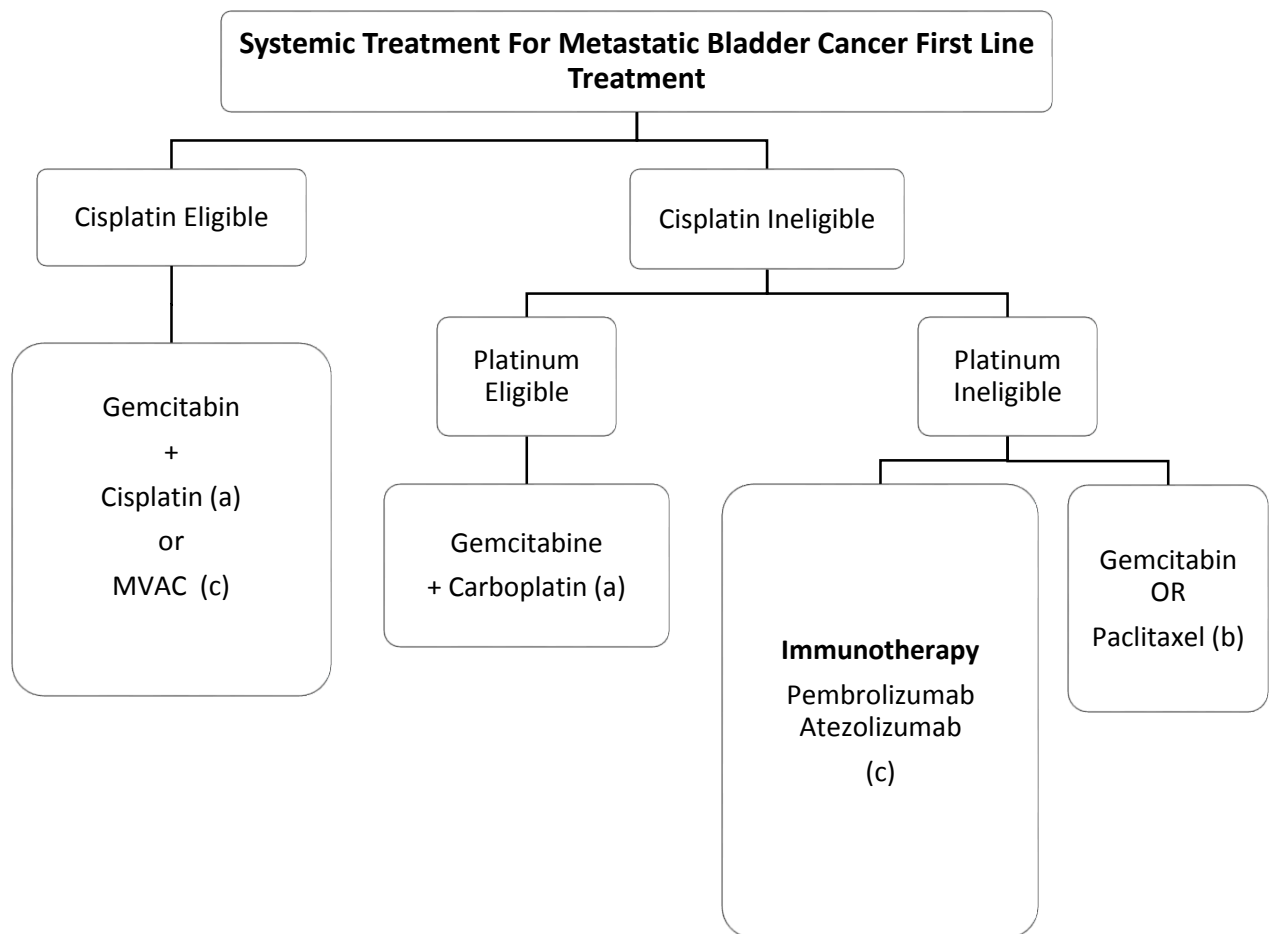
Muscle invasive

**Trans urethral resection of bladder tumour**

Examination under anesthesia and Transurethral resection of Bladder tumour. TURBT findings should include: Number and size of tumours, relation to ureteric orifices, comment on urethra, Prostate and bladder neck (a)  
Following TURBT for low grade NMIBC, one dose of Intravesicle Mitomycin should be administered within the 24hrs of resection (a)







Cisplatin Ineligible is defined as presence of one of the following:

1. ECOG PS  $\geq$  2 OR KPS < 60 to 70 %
2. Creatinine Clearance < 60 mL/min
3. Grade  $\geq$  Hearing Loss
4. Grade  $\geq$  2 Peripheral Neuropathy
5. NYHA Class  $\geq$  III Heart Failure



**Systemic Treatment For Metastatic Bladder Cancer (Second Line And Subsequent Treatment)**

Rechallenge with Platin +Gemcitabine (If previous platin based therapy >12 months back ) (a)

Weekly paclitaxel (b)

Pemetrexed (b)

Docetaxel (b)

Gemcitabine (b)

**Immunotherapy (c)**

Pembrolizumab

Nivolumab

Avelumab

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Inj Gemcitabine 1000 mg /m<sup>2</sup> day 1 and day 8 every 3 weekly till disease progression or unacceptable toxicities

Inj Docetaxel 75 mg/m<sup>2</sup> 3 weekly for 6 cycles

Inj Nivolumab 240 mg every 2 weekly till disease progression or unacceptable toxicities

Inj Pembrolizumab 200 mg every 3 weekly till disease progression or unacceptable toxicities

## TESTICULAR TUMORS

### MANAGEMENT OF TESTICULAR TUMORS

Patient with testicular mass/lower abdominal mass with missing testis

Clinical examination

(Suspicion of tumor)-Undescended testis

Tumor Markers (a)

- AFP, BhCG,LDH (a)
- USG –Scrotum (a)
- CT scan(Thorax, Abdo, Pelvis)(a)
- Semen analysis (b)
- Sperm banking (b)

High Inguinal Orchiectomy (a)

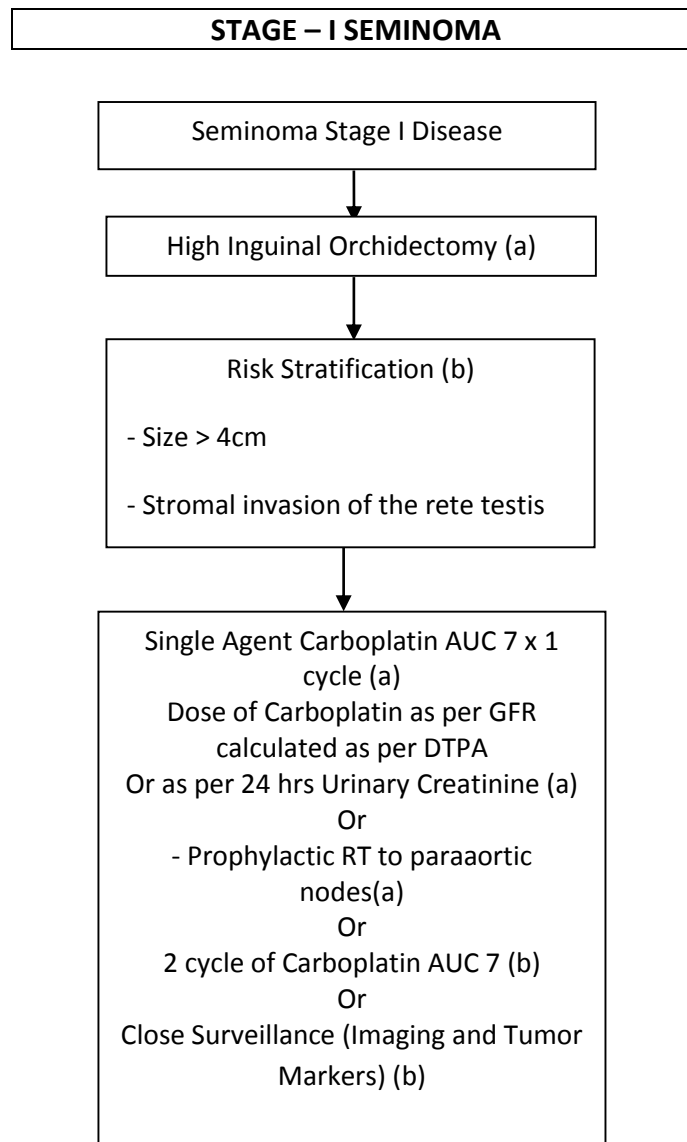
( Scrotal Orchiectomy should not be done)

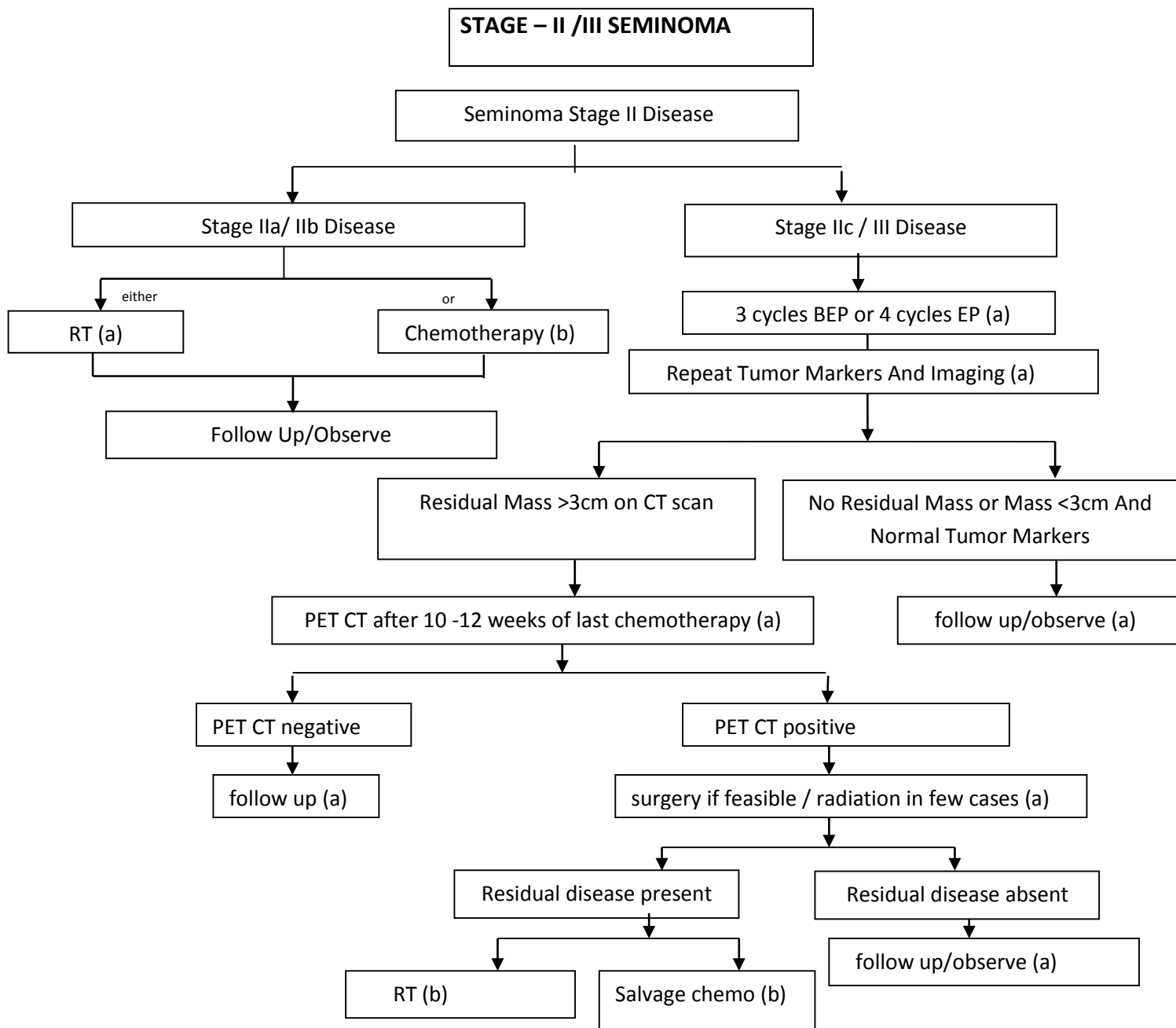
HPR, Post Orchiectomy tumor marker (a)

Staging and risk stratification (a)

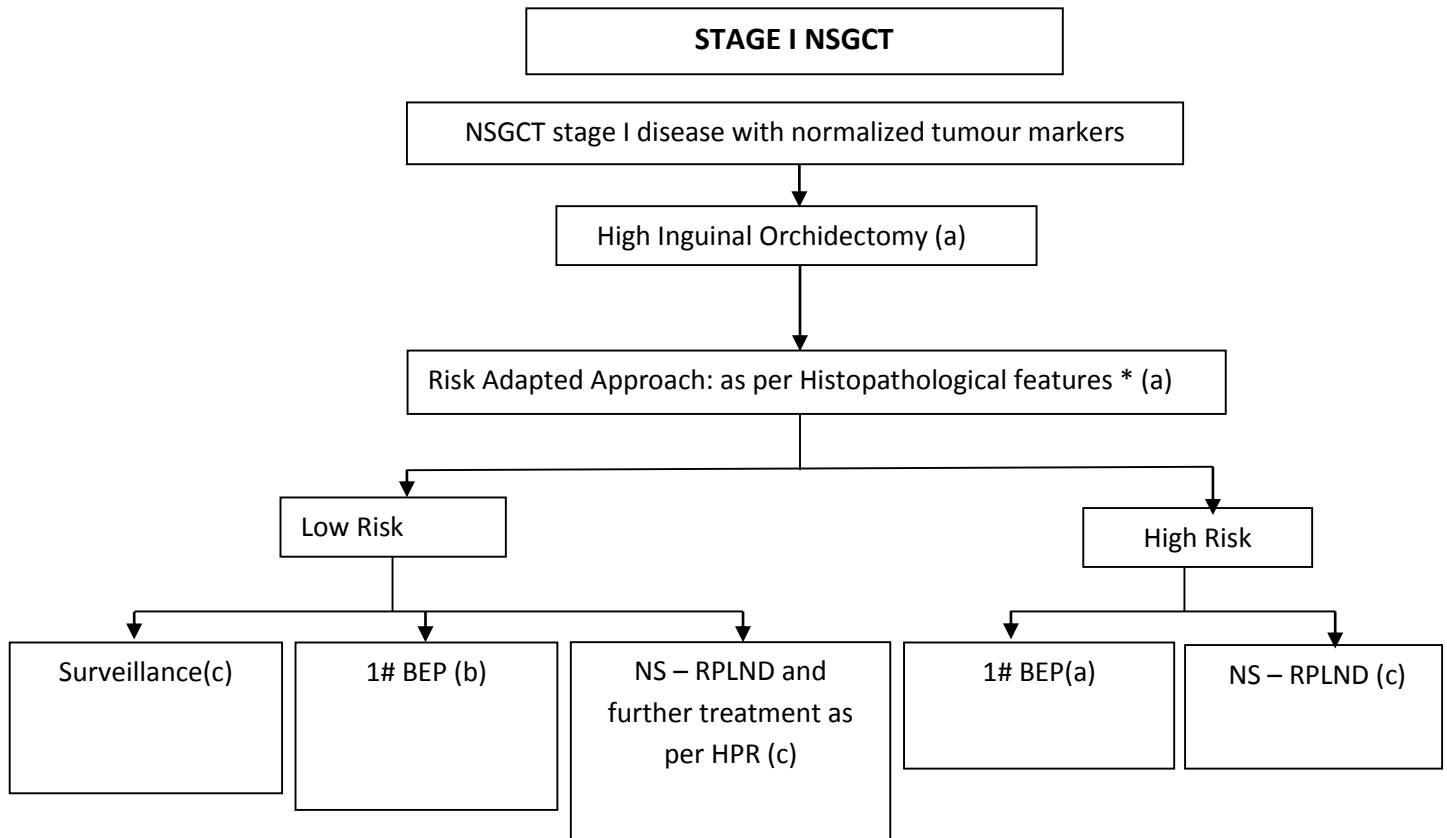
- USG Testis(a)
- Ejaculated sperm preservation if family not completed (b)
- Risk Stratification (a)
- CT ( T+A+P) (a)
- Repeat Tumour Markers after High Inguinal Orchiectomy at least after 7-10 days (a)

- USG guided FNAC (c)
- Onco TESE if ejaculated sperm cryopreservation not feasible.(c)
- Brain Imaging if case of symptoms and patients with metastatic disease with multiple lung metastases or high b-hCG values.(b)
- Fertility investigations: Total testosterone; Luteinising hormone; Follicle-stimulating hormone (c )

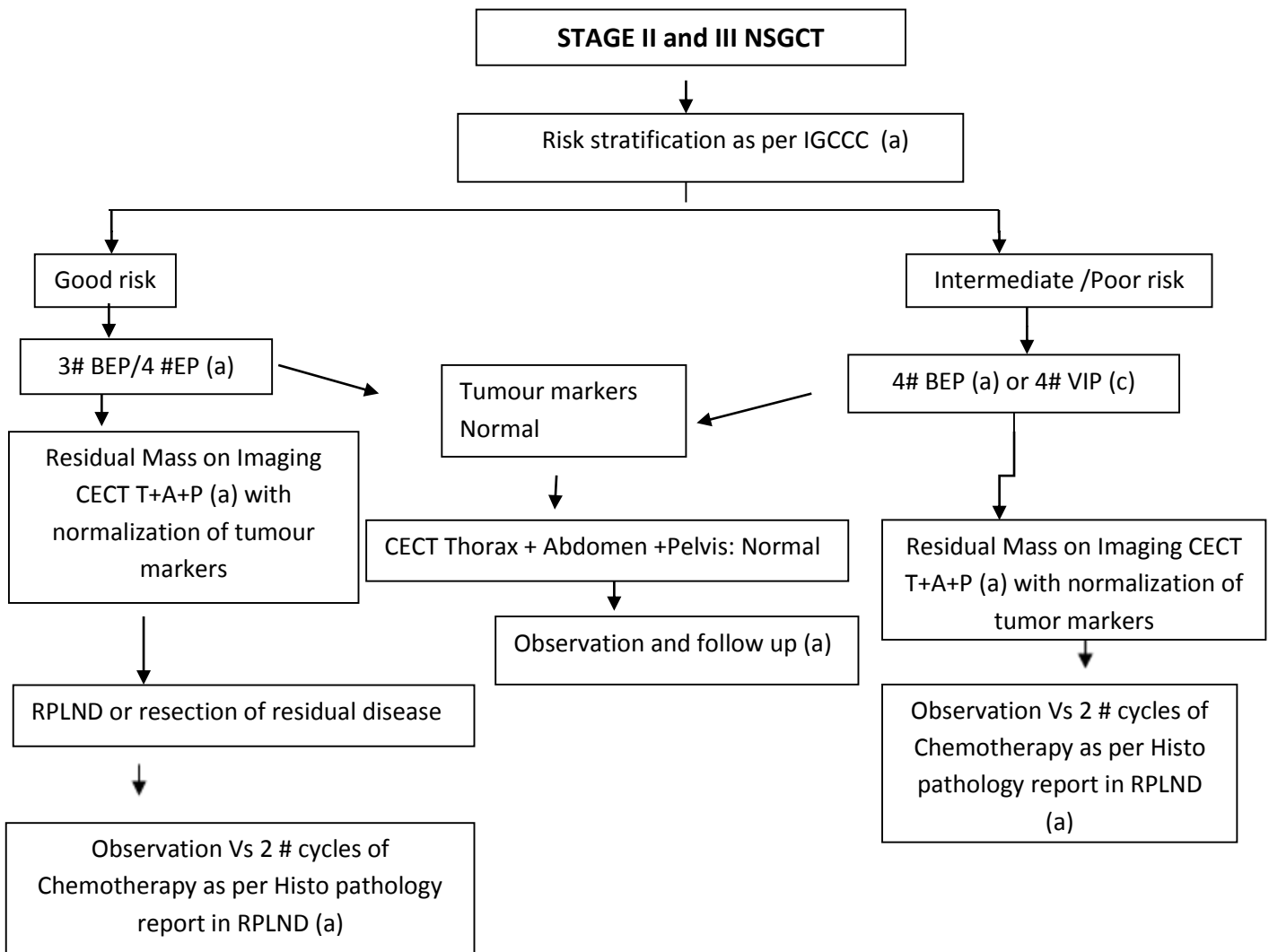




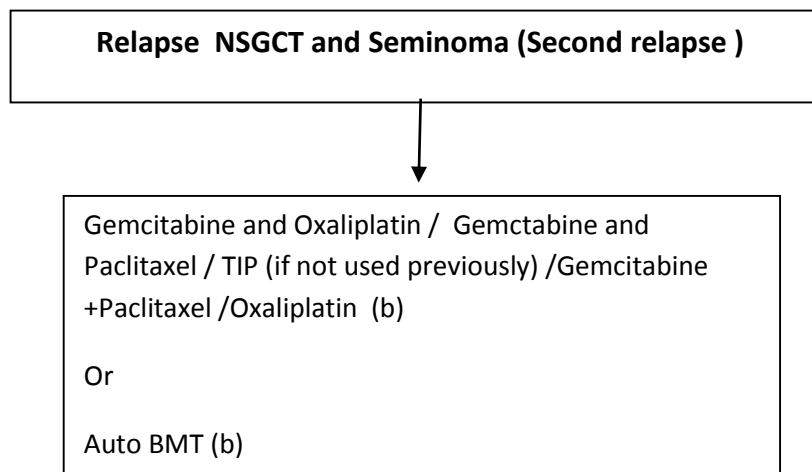
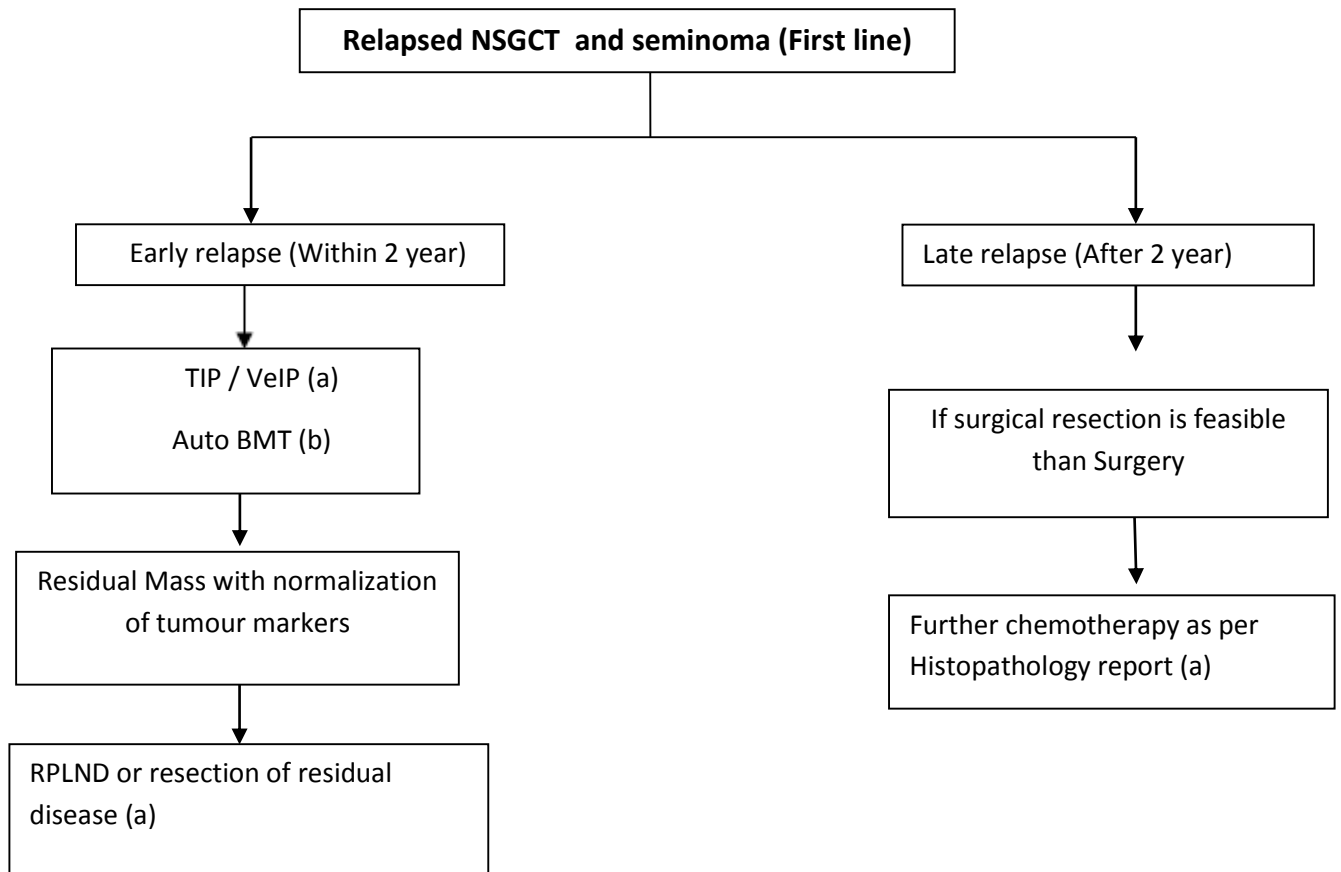
- For Stage II A: RT (a)
- For Stage II B: Chemotherapy (a)
- FDG PET CT for Post chemo seminoma if residual lesion > 3cm (a)
- For PET positive residual masses, consider surgery if feasible preferably at high volume center (a)
- For Stage II A: Chemotherapy (b)
- For Stage II B: RT (b)
- RT to PET positive residual disease if inoperable (c)



\* High risk for stage I includes: Lymphovascular invasion (LVI) + or Embryonal carcinoma component > 40%







**BEP (1st line) :**

Bleomycin: 30 U IV on days 2, 9, and 16 Etoposide: 100 mg/m<sup>2</sup> IV on days 1–5 Cisplatin: 20 mg/m<sup>2</sup> IV on days 1–5. Repeat cycle every 21 days.

Total 3 cycles in Good risk cases or 4 cycles in intermediate and poor risk cases

**EP (1st line)** Etoposide: 100 mg/m<sup>2</sup> IV on days 1–5

Cisplatin: 20 mg/m<sup>2</sup> IV on days 1–5.

Repeat cycle every 21 days. Total 4 cycles in good risk cases

**VIP (First line) :** Inj Etoposide 75mg/m<sup>2</sup> IV over 60 minutes daily, Days 1-5

Inj Mesna 240mg/m<sup>2</sup> IV over 15 minutes before Ifosfamide, then at 4 and 8 hours from start of each Ifosfamide dose, Days 1-5

Inj Cisplatin 20mg/m<sup>2</sup> IV over 60 minutes daily , Days 1-5

Repeat cycle every 3 weeks for 4 cycles.

**Carboplatin Adjuvant (for patients with stage IA, IB seminoma)**

Inj Carboplatin AUC 7 over 30 minutes ,day 1 .

Repeat cycle every 3 weeks for 1-2 cycles

**BEP Adjuvant**

Bleomycin: 30 U IV on days 2, 9, and 16 Etoposide: 100 mg/m<sup>2</sup> IV on days 1–5 Cisplatin: 20 mg/m<sup>2</sup> IV on days 1–5. Repeat cycle every 21 days. Total 1-2 cycles

**VeIP (salvage regimen) :**

Vinblastine: 0.11 mg/kg IV on days 1 and 2

Ifosfamide: 1,200 mg/m<sup>2</sup> IV on days 1–5

Cisplatin: 20 mg/m<sup>2</sup> IV on days 1–5

Mesna: 400 mg/m<sup>2</sup> IV, given 15 minutes before first ifosfamide dose, then 1,200 mg/m<sup>2</sup>/day IV continuous infusion for 5 days

Repeat cycle every 21 days for 4 cycles

**TIP regimen (Salvage regimen):**

Inj Paclitaxel 250mg /m<sup>2</sup> 24 hour infusion Day 1

Ifosfamide 1500 mg/m<sup>2</sup> Day 2 to day 5

Mesna 500 mg/m<sup>2</sup> just before Ifosfamide and at 4 and 8 hours Day2 to day 5.

Cisplatin 25 mg/m<sup>2</sup> Day2 to day 5 , for 4 cycles

**Or**

Inj Paclitaxel 175 mg /m<sup>2</sup> 3 hour infusion Day 1

Inj Ifosfamide 1500 mg/m<sup>2</sup> Day 2 to day 5

Inj Mesna 500 mg/m<sup>2</sup> just before Ifosfamide and at 4 and 8 hours Day2 to day 5.

Inj Cisplatin 25 mg/m<sup>2</sup> Day 2 to day 5 , for 4 cycles

**Gemcitabine + Paclitaxel + Oxaliplatin :**

Inj Paclitaxel 80mg/m<sup>2</sup> IV over 60 minutes, Days 1,8

Inj Gemcitabine 800mg/m<sup>2</sup> IV over 30 minutes, Days 1,8

Inj Oxaliplatin 130mg/m<sup>2</sup> IV over 2 hours Day 1

Repeat cycle every 3 weeks for 8 cycles

**Gemcitabine + Oxaliplatin :**

Inj Gemcitabine 1000-1.250mg/m<sup>2</sup> IV over 30 minutes Days 1,8.

Inj Oxaliplatin 130mg/m<sup>2</sup> IV over 2 hours Day 1

Repeat cycle every 3 weeks for 4-6 cycles

**Gemcitabine + Paclitaxel**

Inj Paclitaxel 100mg/m<sup>2</sup> IV over 60 minutes, Days 1,8,15.

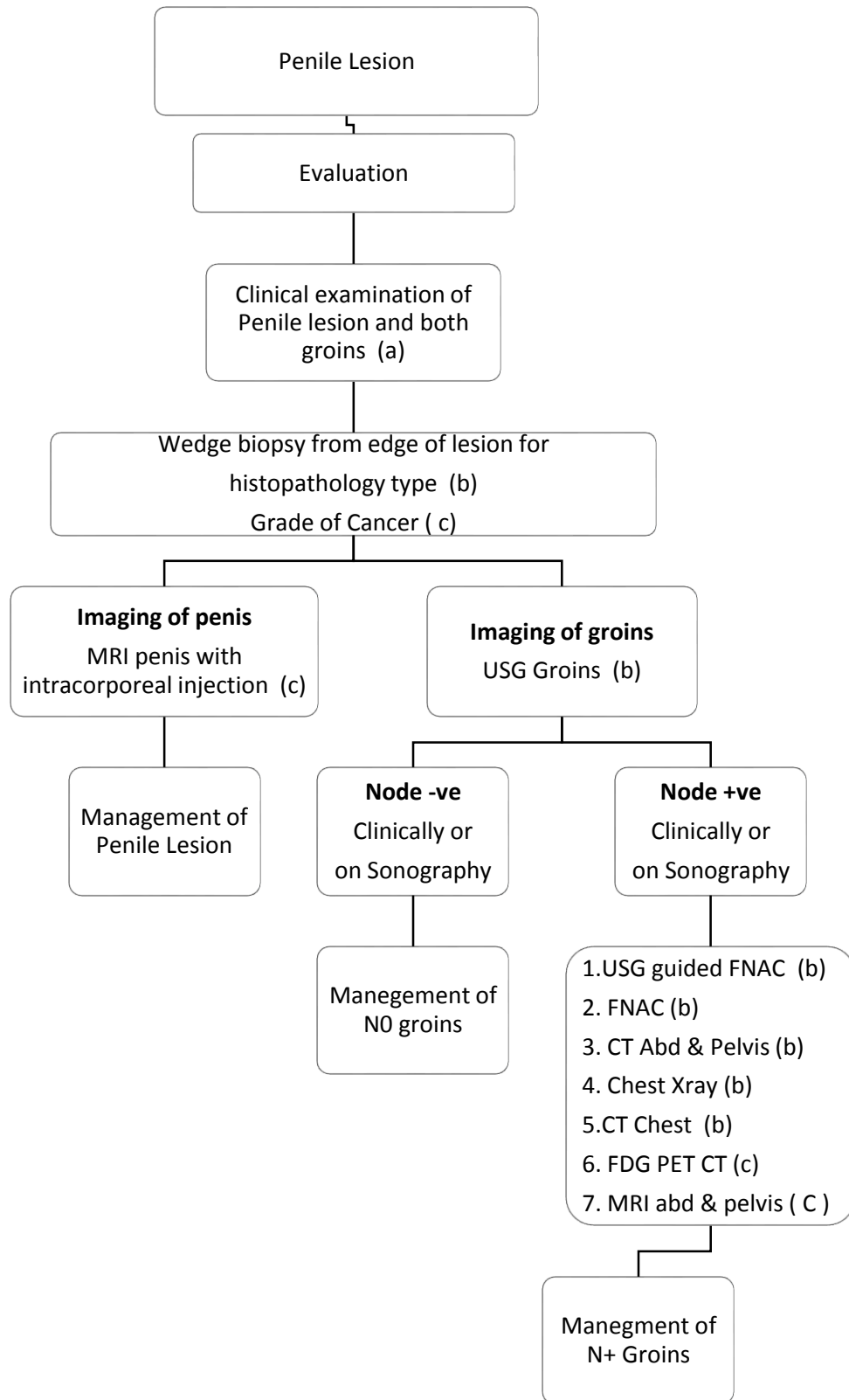
Inj Gemcitabine 1,000mg/m<sup>2</sup> IV over 30 minutes, Days 1,8,15

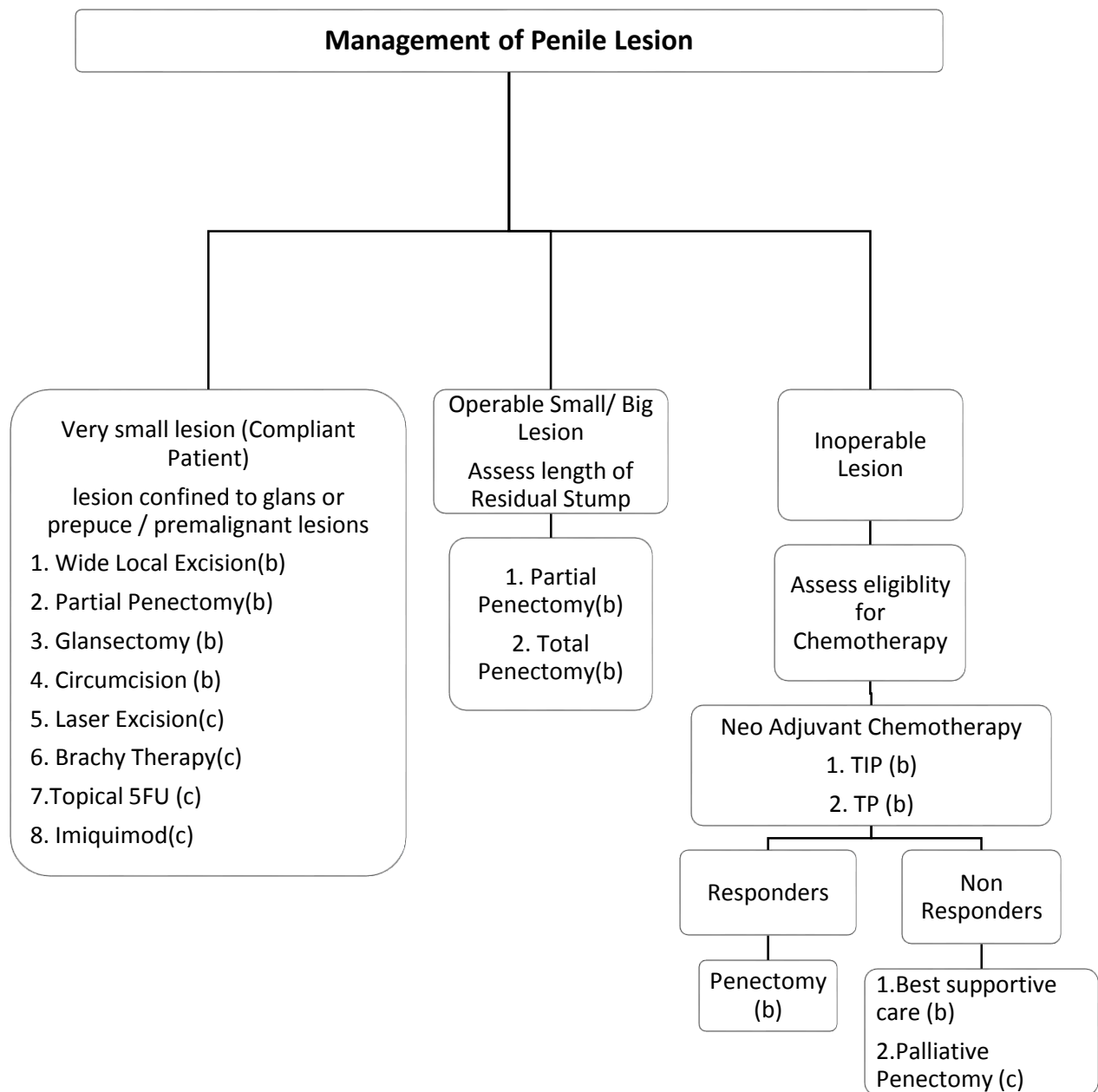
Repeat every 4 weeks for 6 cycles.

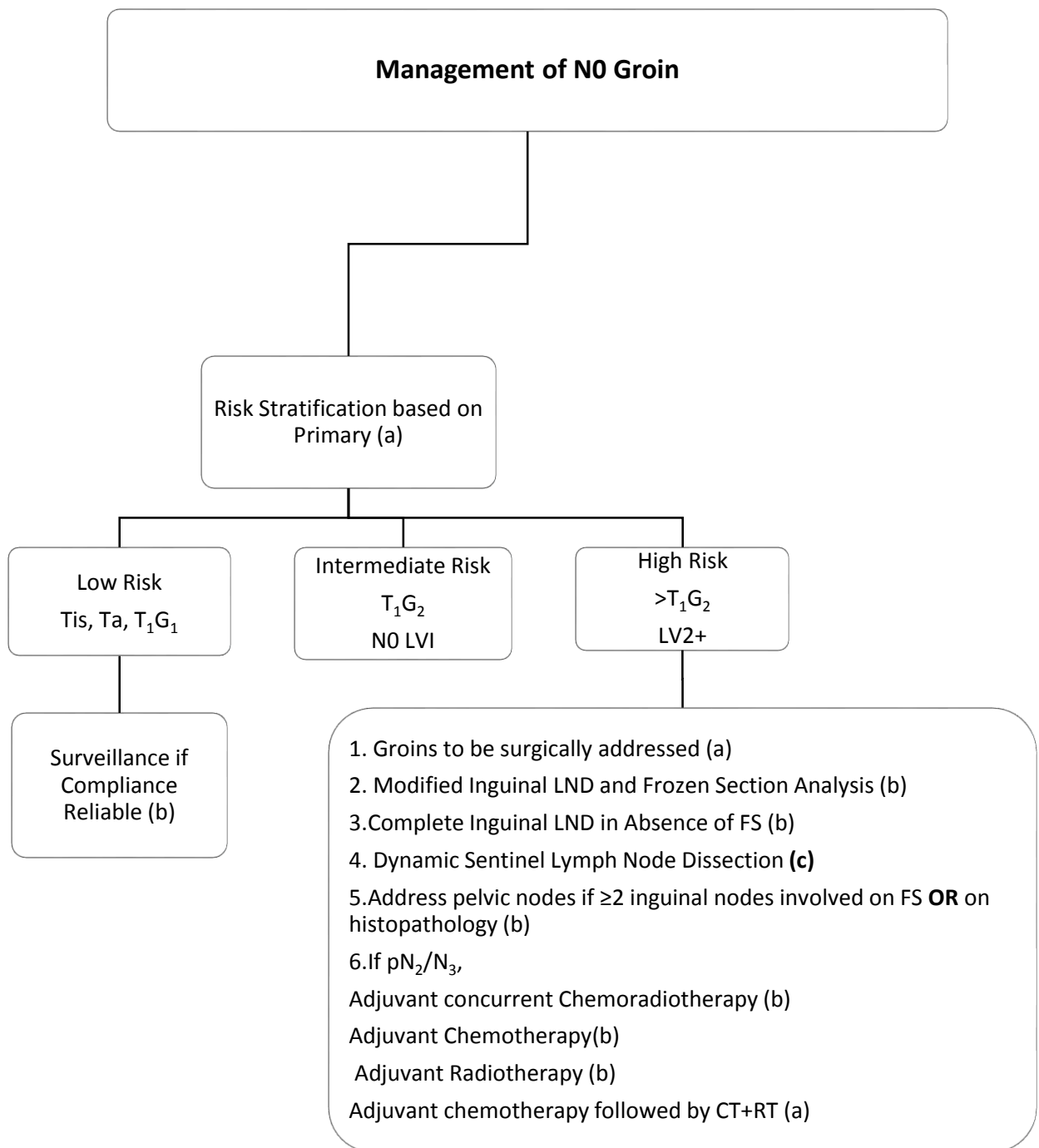
**Etoposide (oral) :** Tab Etoposide 50-100 mg orally daily, Days 1-21.

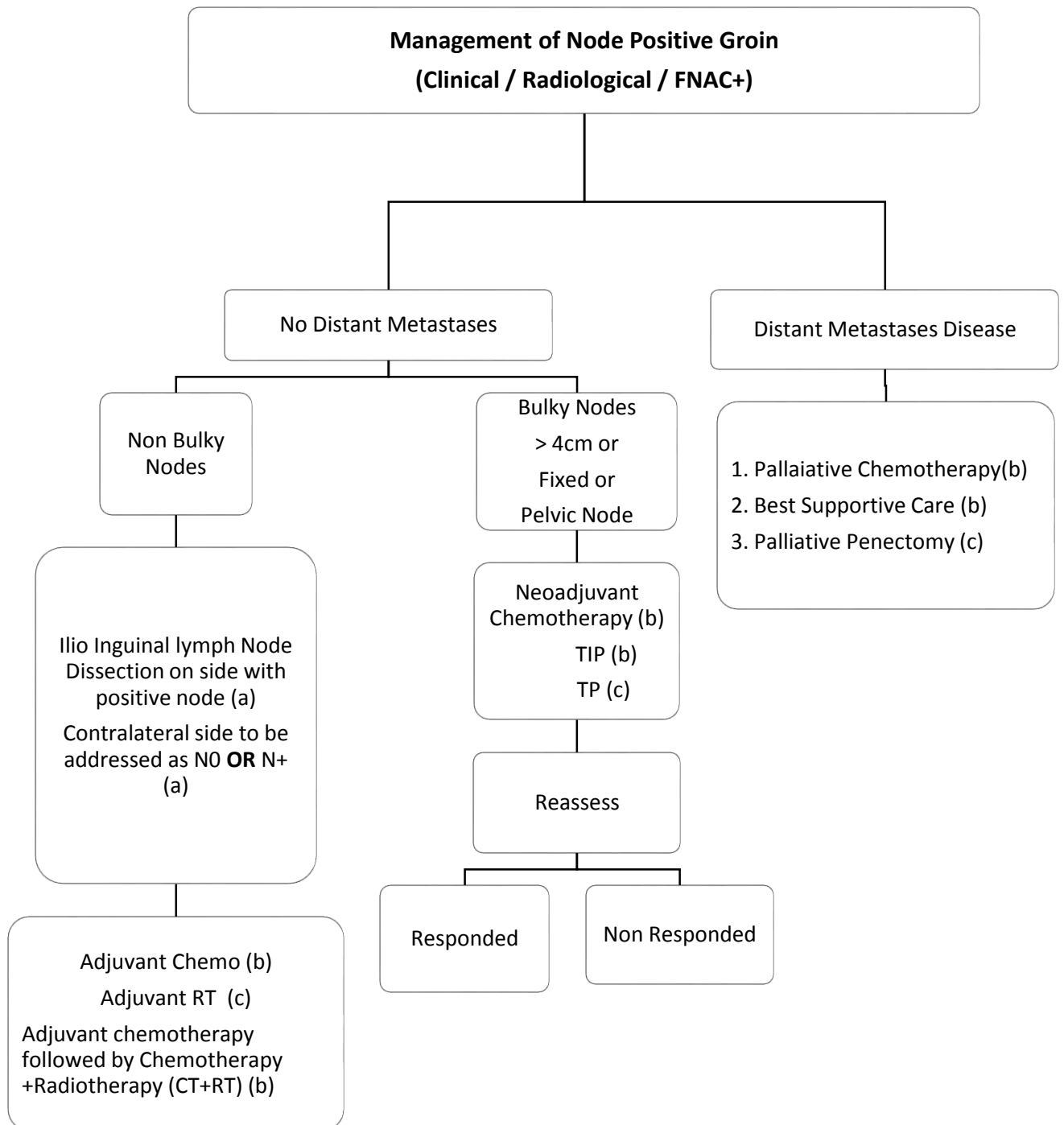
Repeat cycle every 4 weeks till disease progression

**PENILE CANCER**









**Adjuvant Chemotherapy :**

Inj Cisplatin 75 mg /m<sup>2</sup> +Inj Paclitaxel 175 mg/m<sup>2</sup> every 3 weekly for 4 cycles

OR

Inj Carboplatin AUC 5 + Inj Paclitaxel 175 mg/m<sup>2</sup> every 3 weekly for 4 cycles

OR

**TIP:**

Inj Paclitaxel 175 mg/m<sup>2</sup> IV over 3 hours on Day 1, Inj Ifosfamide 1200 mg/m<sup>2</sup> IV over 2 hours on Days 1–3 , Inj Cisplatin 25 mg/m<sup>2</sup> IV over 2 hours on Days 1–3 for 4 cycles

OR

Inj 5-FU Continuous infusion of 800–1000 mg/m<sup>2</sup>/day IV on Days 1–4 or Days 2–5

Cisplatin 70–80 mg/m<sup>2</sup> IV on Day 1 for 4 cycles

**Neoadjuvant chemotherapy :**

TIP : Inj Paclitaxel 175 mg/m<sup>2</sup> IV over 3 hours on Day 1, Inj Ifosfamide 1200 mg/m<sup>2</sup> IV over 2 hours on Days 1–3 , Inj Cisplatin 25 mg/m<sup>2</sup> IV over 2 hours on Days 1–3 for 4 cycles

**Palliative chemotherapy:**

Inj Cisplatin 75 mg /m<sup>2</sup> + Inj Paclitaxel 175 mg/m<sup>2</sup> every 3 weekly for 6 cycles

OR

Inj Carboplatin AUC 5 + Inj Paclitaxel 175 mg/m<sup>2</sup> every 3 weekly for 6 cycles

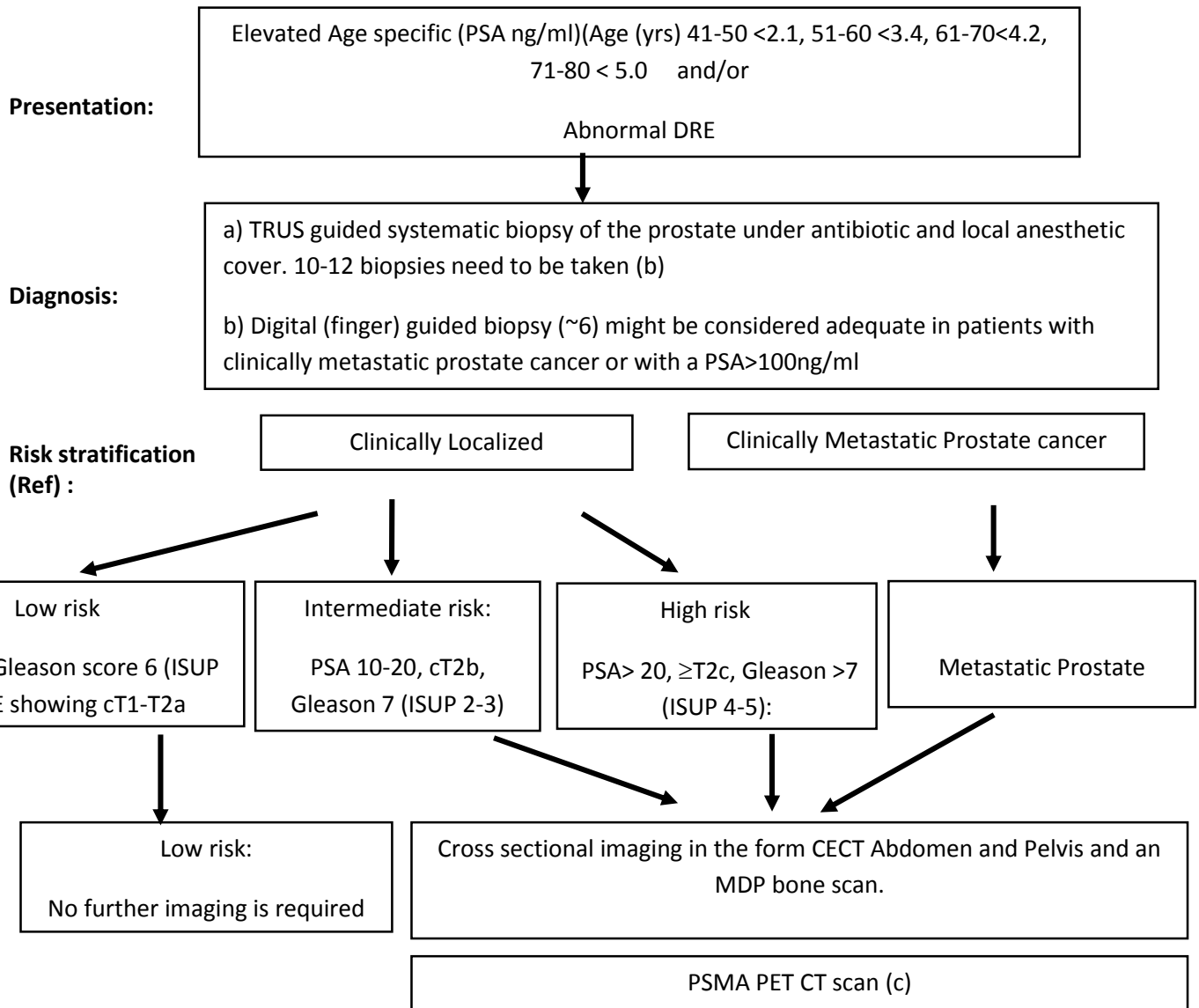
OR

Inj Paclitaxel 80 mg /m<sup>2</sup> weekly till disease progression

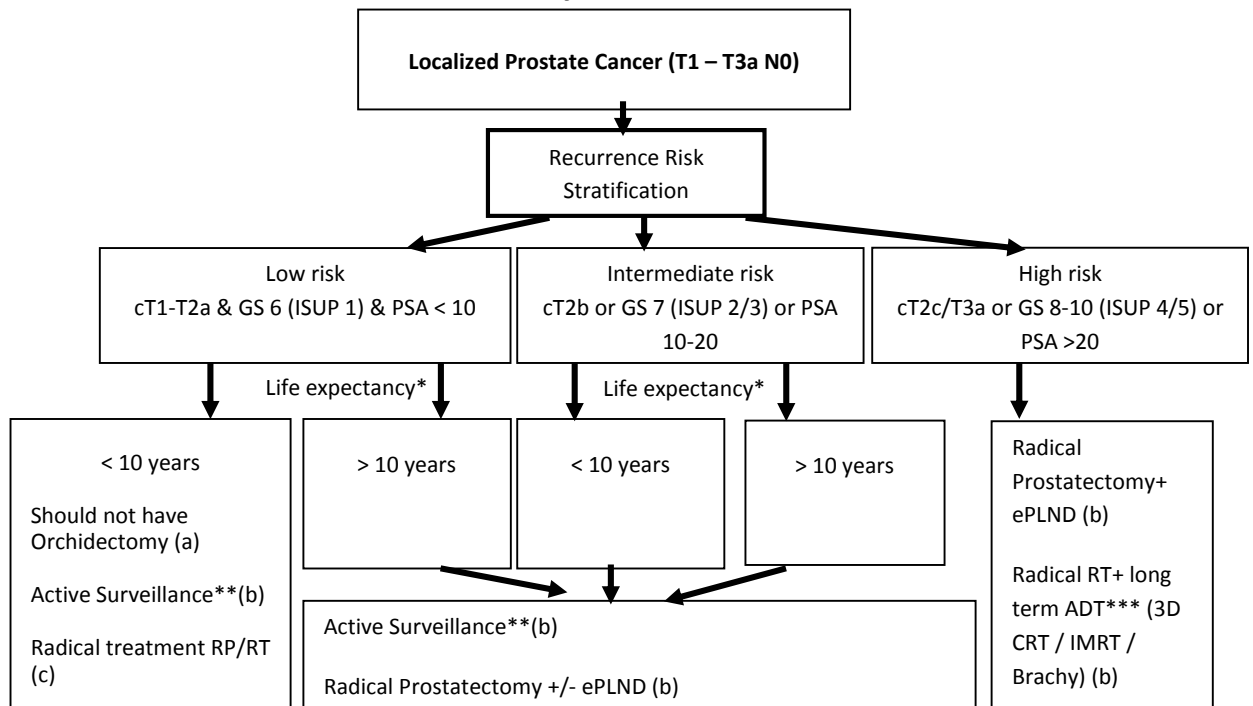


**PROSTATE CANCER**

**Investigations for Prostate cancer**



## Treatment Pathway for Localized disease



\*Life expectancy: Estimation of life expectancy has to be based on based patients' comorbidity and health assessment using validated tools like Geriatric 8 (G8) screening tool (b)

\*\*Active surveillance: All patients need a mpMRI of the prostate within 3 months of biopsy before formal confirmation of Active surveillance pathway

- Any abnormality noted on mpMRI needs to be further assessed using targeted biopsy before confirmation of active surveillance especially in patients with life expectancy of >10 yrs.

**Follow up :** PSA testing every 3 months in the first year

- DRE every 12 months
- mpMRI every 12-18 months

**Progression:** PSA rise greater 50% in 12 months or PSA doubling time of <3 yrs warrants repeat biopsy or radical treatment

- Any significant rise in PSA, or abnormal DRE or mpMRI warrants a biopsy or consideration of radical treatment

### \*\*\*ADT: Androgen Deprivation therapy

- Short term ADT: Neo / concomitant / adjuvant for 4-6 months
- Long term ADT : Neo / concomitant / adjuvant for 2-3 years

### Radical RT : Radical Radiation therapy

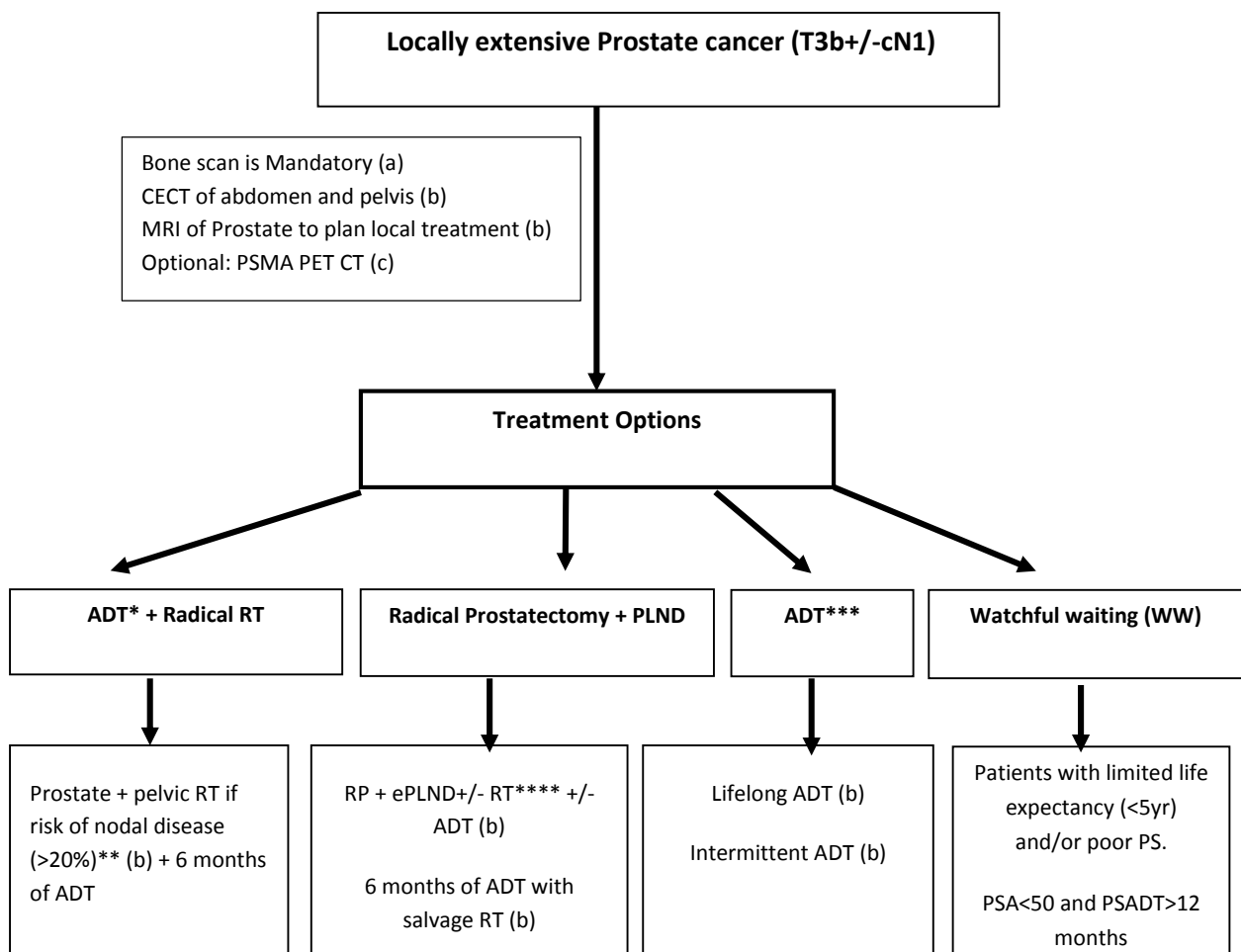
- Low Risk: 3 D CRT / IMRT / Brachytherapy : 70-74Gy
- Intermediate Risk : 3 D CRT / IMRT +/- Brachytherapy : 74 Gy /30 fractions or equivalent
- High Risk: 3 D CRT / IMRT +/-Brachytherapy : >74 using conventional / moderate hypofractionation
- SBRT for low and Intermediate risk prostate cancer (c)

*(RT Doses > 74 Gy mandates a component of Image Guided Radiotherapy)*

### Radical Sx : Radical Surgery

- RP: Radical prostatectomy
- ePLND: Pelvic lymph nodal dissection: When the risk of lymph node involvement is >5% either by using nomogram or Roach formula. Assessment of nodal risk using Roach formula:  $N+=2/3*PSA+(GS-6) X10$

**Monthly Intravenous Zoledronic acid is not required in Localised Prostate cancer treatment (a)**



**Monthly Intravenous Zoledronic acid is not required in Localised/Locally extensive Prostate cancer treatment (a)**

\*ADT in locally advanced disease is started as neo-adjuvant treatment and is continued for 18-36 months' overall

\*\*Assessment of nodal risk using Roach formula:  $N+=2/3*PSA+(GS-6) \times 10$

\*\*\* In patients not fit and not willing for radical treatment

\*\*\*\* Neoadjuvant ADT is not recommended before radical prostatectomy (a)

\*\*\*\* Adjuvant RT after RP: If Capsule invasion or cut margins positive on final HPR (Ref.: 14,15) or PSA persistence post radical prostatectomy (b)

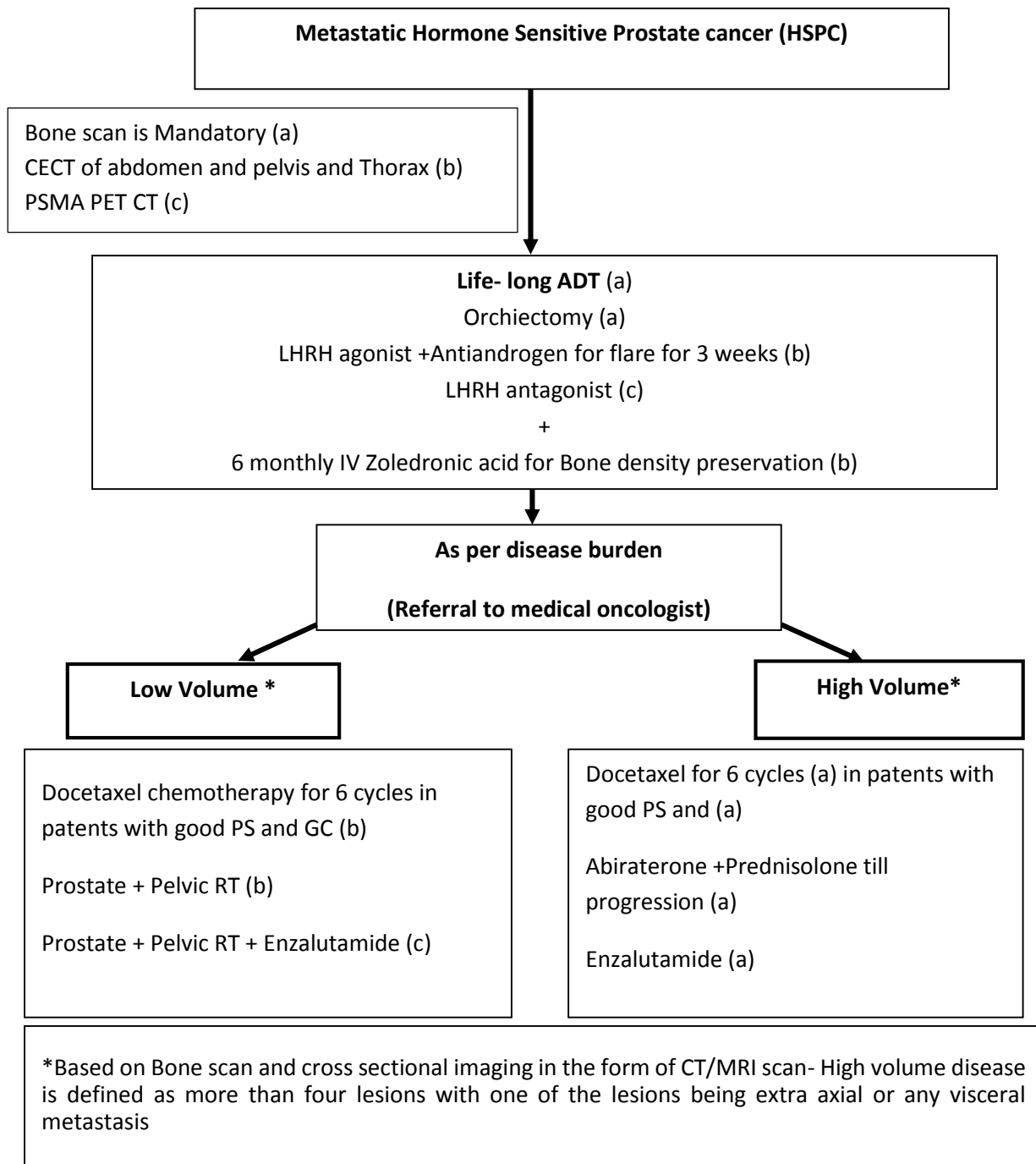
Early Salvage RT: Radiotherapy in post-surgery setting with three consecutive raises of PSA with PSA 0.2-0.5 ng/ml (b)

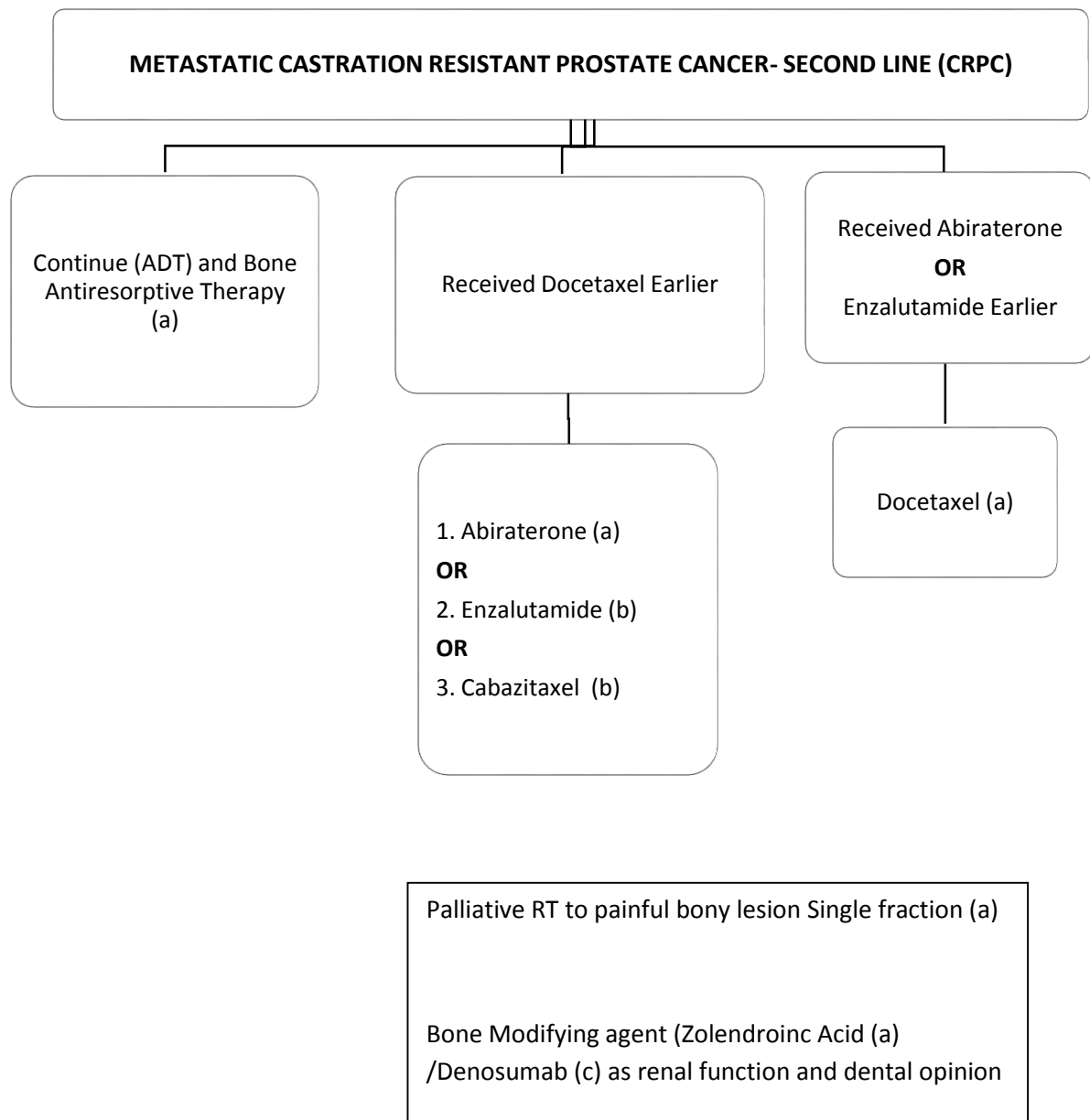
In staging of post primary treatment recurrence disease PSMA PET is the investigation of choice (b)

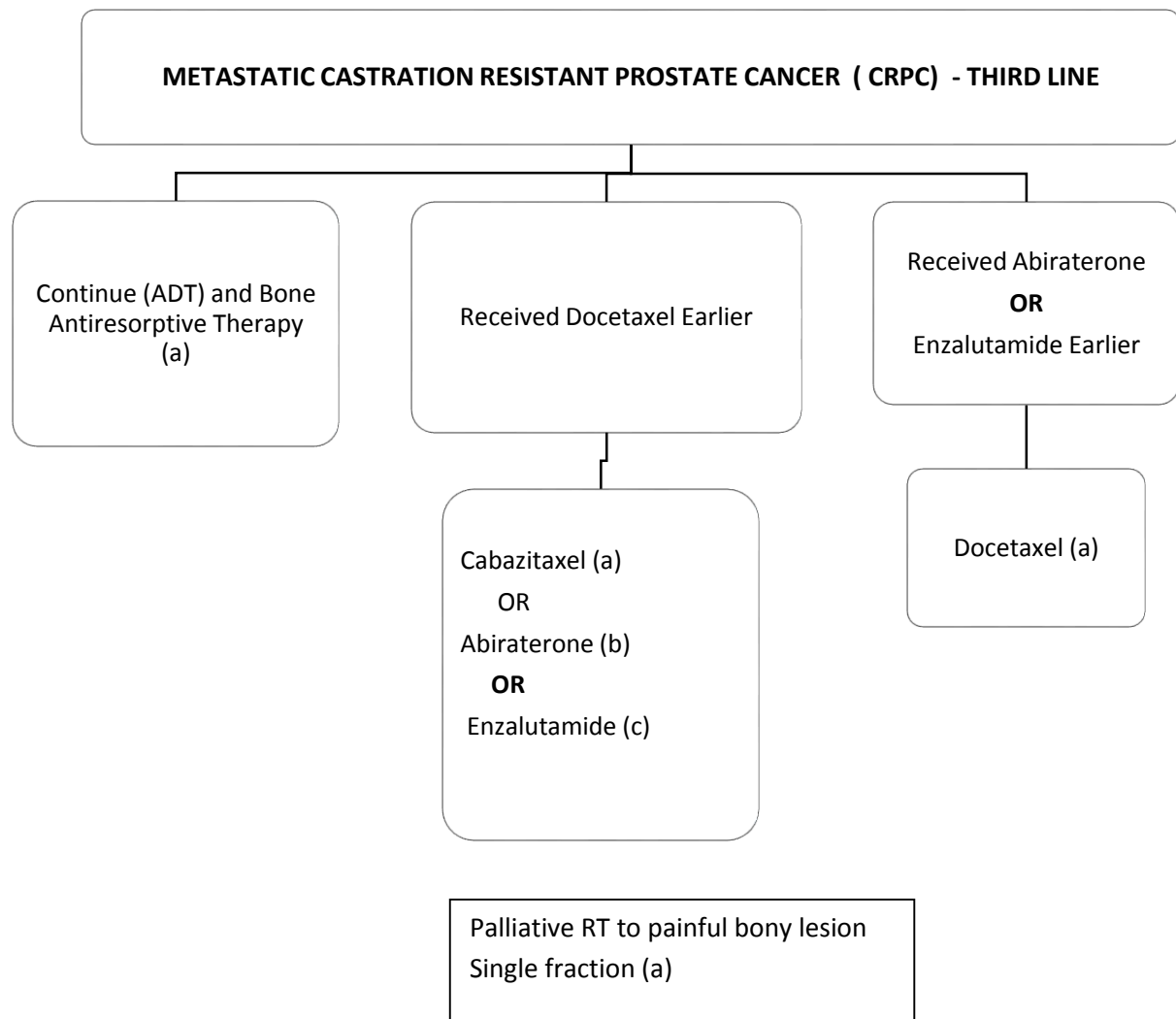
Post-operative RT to Prostate bed: 60-66 Gy with 3D CRT / IMRT

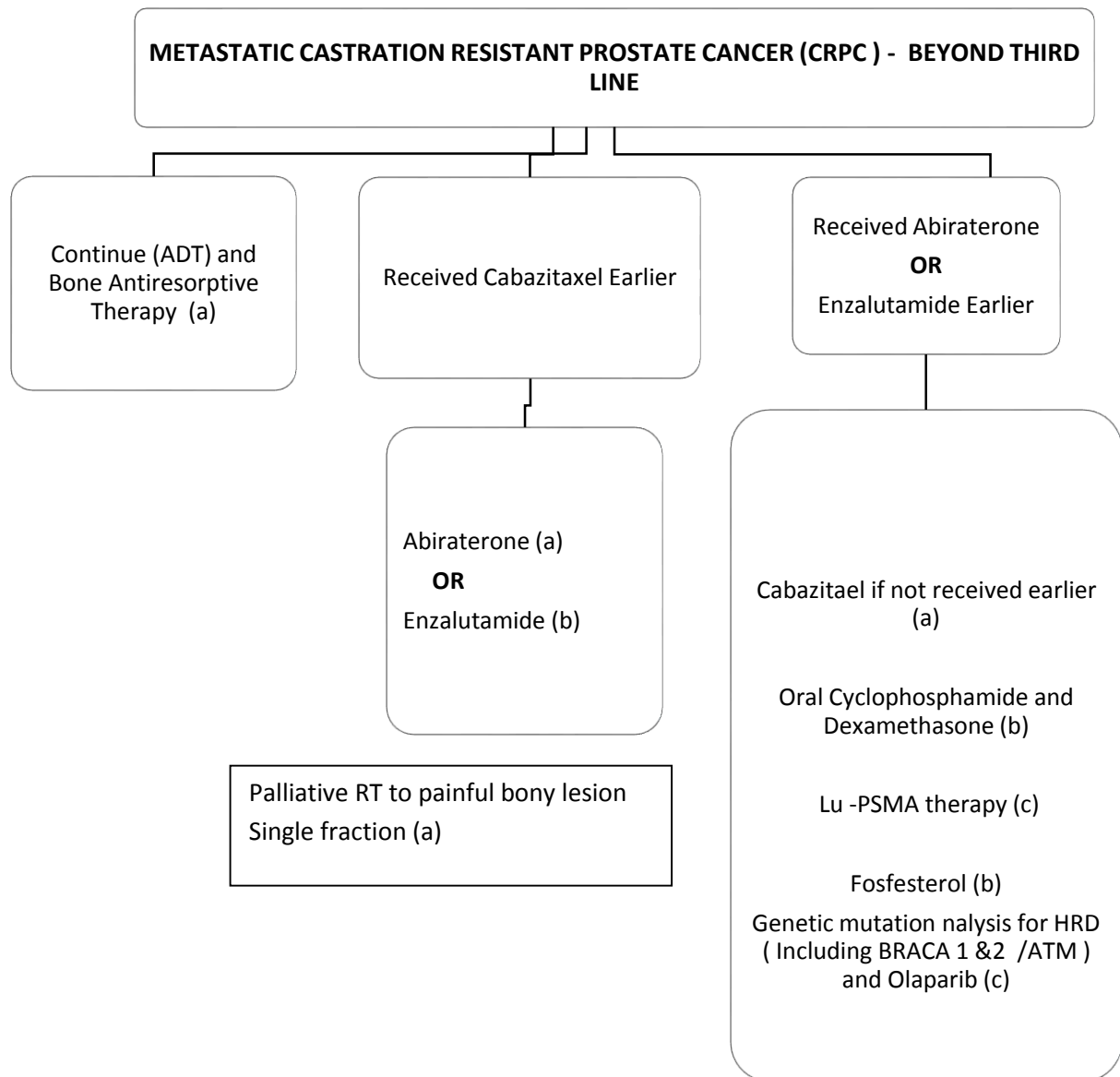
**RT: Radiation therapy**

- ▶ Prostate only fields include Prostate + SV with margins
- ▶ Prostate + pelvic fields include Prostate + SV with margins and pelvic nodal regions









**GnRH Agonist:**

Leuprolide:

Leuprolide Depot 7.5 mg (monthly): 7.5 mg every month or

Leuprolide Depot 22.5 mg (3 month): 22.5 mg every 12 weeks or

Leuprolide Depot 30 mg (4 month): 30 mg every 16 weeks or

Leuprolide Depot 45 mg (6 month): 45 mg every 24 weeks

OR

Leuprolide 7.5 mg monthly or 22.5 mg every 3 months or 30 mg every 4 months or 45 mg every 6 months deep subcutaneous injection

OR

Goserelin :

3.6 mg every monthly or 10.8 mg every 3 monthly deep subcutaneous

**GnRH antagonist:**

Degarelix: Loading dose: 240 mg administered as two 120 mg injections

Maintenance dose: 80 mg injection every 28 days (beginning 28 days after initial loading dose)

Tab Bicalutamide 50 mg Daily for 3 weeks along with GnRH agonist

Abiraterone 1000mg orally once daily (250 mg 4 tablets or 500 mg 2 tablet )

+

Prednisolone 5mg orally once a daily for hormone sensitive prostate cancer (HSPC)

Or

Prednisolone 5mg orally twice daily for castrate resistant prostate cancer (CRPC)

Cycle Frequency: Daily until disease progression

Enzalutamide 160mg orally once daily (40 mg ,4 tablets daily) Cycle Frequency: Daily until disease progression

Docetaxel 75mg/m<sup>2</sup> in 250ml sodium chloride 0.9% infusion over 1 hour. Every 21 days maximum 6 cycles (IN HSPC) with or without Tab Prednisolone 10 mg mg OD

Or

Docetaxel 50 mg/m<sup>2</sup> in 250ml sodium chloride 0.9% infusion over 1 hour . Every 15 days



maximum 9 cycles (IN HSPC) with or without Tab Prednisolone 10 mg OD

Or

Docetaxel 75mg/m<sup>2</sup> in 250ml sodium chloride 0.9% infusion over 1 hour . Every 21 days (IN CRPC) with Tab Prednisolone 10 mg OD till progression or tolerance

Or

Docetaxel 50 mg/m<sup>2</sup> in 250ml sodium chloride 0.9% infusion over 1 hour . Every 15 days (IN CRPC) with Tab Prednisolone 10 mg OD progression or tolerance

Or

Docetaxel 30 mg/m<sup>2</sup> in 250ml sodium chloride 0.9% infusion over 1 hour . Every weekly (IN CRPC) with Tab Prednisolone 10 mg OD progression or tolerance

Cabazitaxel 25mg/m<sup>2</sup> or 20 mg /m<sup>2</sup> in 250ml sodium chloride 0.9% IV infusion over 1 hour with Tab

Prednisolone 10mg orally daily (IN CRPC )

Tab Olaparib 300 mg BD till progression

Tab Cyclophosphamide 50 mg OD day1 to day 21 cycle every 28 days to be continued till progression +

Tab Dexamethasone 0.5 mg OD to be continued till progression

Tab Fosfesterol 120 mg BD /TDS till progression

#### **Bone modifying agent ( As per renal function )**

Inj Zoledronic acid 4 mg IV every 4 weekly (In CRPC patients with bony metastasis)

Inj Zoledronic acid 4 mg IV every 6 monthly (In HSPC patients or patients receiving ADT with higher risk of osteoporosis)

Inj Denosumab 120 mg subcutaneous every 4 weekly in CRPC with bony metastasis

Inj Denosumab 60 mg subcutaneous as a single dose, once every 6 months in androgen deprivation therapy-induced bone loss in males with prostate cancer with higher risk of osteoporosis

## ANNEXURE -1. RADIOLOGY SYNOPTIC REPORTING FORMATS

### **RENAL MASS CT**

Technique: Plain and contrast enhanced CT study of the abdomen and pelvis was performed with special attention to the urinary system. Cortico-medullary, Nephrogenic and Delayed Phases were included in contrast enhanced study.

Clinical details:

Comparison if any:

Findings:

**Involved Kidney:**

**No. of lesions:**

**Lesion 1: (repeat similarly for all lesions)**

Laterality: Right / Left

Morphology: Solid / Cystic / Mixed

Location: Upper pole / Interpolar region / Lower pole; Anterior / Posterior

Size:

Relation to polar lines: Crosses / Does not cross the upper/lower polar lines; if crosses, then mention less than or more than 50%

Endophytic / Exophytic: If exophytic, then mention less than or greater than 50%

Relation to collecting system: Mention if involved or distance from collecting system if uninvolved. Mention ureteric involvement if any.

Locoregional extent: Perinephric / Anterior and posterior paranephric spaces / Peritoneum / Adjacent structures (adrenal, psoas, pancreas, duodenum, vertebrae, liver, any other).

Rest of the renal parenchyma: Mention nephrogram and excretory properties. Mention presence and grade of hydronephrosis.

**Vascular involvement:**

Renal vein: Number / Variant course if any (eg retroaortic) / Mass effect / Involvement / Thrombosis

Renal artery: Number / Division (Prehilar or Hilar) / Mass effect / Involvement / Thrombosis /

IVC: Mass effect / Involvement / Thrombosis / Extent

Contralateral renal vein: Mass effect / Involvement / Thrombosis / Extent

**Ipsilateral Ureter:**

**Nodes:**

Retroperitoneal / Pelvic / Retrocrural / Others

**Contralateral Kidney and Ureter:**

**Ureters:**

**Urinary bladder:**

**Adrenals:**

**Liver:**

**Peritoneum and Ascitis:**

**Bones:**

**Visualized Lung bases:**

**Rest of the abdominal and pelvic viscera:**

Gall bladder, Pancreas, Spleen, Stomach and Bowel loops, Uterus and ovaries (in females), Prostate and seminal vesicles (in males), Abdominal wall.

Impression:

Include mass laterality, R.E.N.A.L. nephrometry score, BOSNIAK type (when relevant), vascular involvement, metastatic involvement.

Mention interval change if compared with previous study.

## **URINARY BLADDER CT**

Technique: Plain and contrast enhanced CT study of the abdomen and pelvis was performed with special attention to the urinary system. Corticomedullary, Nephrogenic and Delayed Phases were included in contrast enhanced study.

Clinical details:

Comparison if any:

Findings:

**Urinary Bladder:**

**No. of lesions:**

**Lesion 1: (repeat similarly for all lesions)**

Morphology: Intraluminal (exophytic) / Intramural (endophytic). If intraluminal, mention if pedunculated or broad-based

Size:

Location: Dome / Trigone / Neck / Anterior / Posterior / Lateral walls

Ureterovesical junction involvement: If yes, mention presence and grade of hydronephrosis

Extravesical extent: Perivesical space / Urethra / Ureters / Prostate and seminal vesicles (in males) / Uterus, ovaries and vagina (in females) / Rectum / Pelvic bowel loops / Any other.

Rest of the bladder walls:

**Nodes:**

Pelvic / Retroperitoneal / Others

**Kidneys and Ureters:**

**Adrenals:**

**Liver:**

**Peritoneum and Ascitis:**

**Bones:**

**Visualised Lung bases:**

**Rest of the abdominal and pelvic viscera:**

Gall bladder, Pancreas, Spleen, Stomach and Bowel loops, Uterus and ovaries (in females), Prostate and seminal vesicles (in males), Abdominal wall.

Impression: Include mass location, extravesical extension, obstructive uropathy if present, metastatic involvement.

Mention interval change if compared with previous study.

## **URINARY BLADDER MRI**

Technique: Multiparametric MRI of the urinary bladder was performed.

Clinical details: Include recent cystoscopic appearance, biopsy findings, treatment received

Comparison if any:

Findings:

**Urinary Bladder:**

**No. of lesions:**

**Lesion 1: (repeat similarly for all lesions)**

Size:

Location: Dome / Trigone / Neck / Anterior / Posterior / Lateral walls

Ureterovesical junction involvement: If yes, mention presence and grade of hydroureteronephrosis

Morphology: Intraluminal (exophytic) / Intramural (endophytic). If intraluminal, mention if pedunculated or broad-based (presence of stalk on T2W images)

Inner layer on T2WI: Normal / Thickened

Muscularis integrity on T2W images: Intact / Interrupted / Extravesical extension of mass.

Muscularis integrity on DCE findings: No enhancement / Inner layer early enhancement / Muscularis early enhancement

Muscularis integrity on DWI findings: Inner layer restricted diffusivity / Muscularis restricted diffusivity

Extravesical extent: Perivesical space / Urethra / Ureters / Prostate and seminal vesicles (in males) / Uterus, ovaries and vagina (in females) / Rectum / Pelvic bowel loops / Any other.

Rest of the bladder walls:

**Nodes:**

Pelvic / Retroperitoneal / Others

**Bones:**

Impression:

Include mass location and VIRADS category for each lesion.

Mention extravesical extension and metastatic involvement.

Mention interval change if compared with previous study.

Recommendation if any: Biopsy / Follow up / Any other investigation

## **TESTIS MALIGNANCY CT**

Technique: Plain and contrast enhanced CT study of the chest, abdomen and pelvis was performed.

Clinical details:

Comparison if any:

Findings:

**Testis:** Mass laterality and size

**Nodes:**

Retroperitoneal – discrete / conglomerate / infiltrative, necrotic / non-necrotic, calcified / non-calcified; Mention abutment or encasement of aorta / IVC / other vessels; angle of contact (<90, 90-180, >180 degrees)

Pelvic

Inguinal:

Other abdominopelvic nodes:

Mediastinal

Hilar

Supraclavicular

Axillary

Other intrathoracic nodes:

**If post-surgical for follow-up:** Lymphoceles / Collections

**Metastatic involvement:**

Liver:

Adrenals:

Lungs:

Bones:

Peritoneum and Ascitis:

**Rest of the viscera:** Gall bladder, Pancreas, Spleen, Kidneys, Stomach and Bowel loops, Prostate and seminal vesicles, Mediastinum, Heart and Great vessels, Trachea and airways, Thyroid, Thoraco-abdominal wall

Impression:

Include testicular mass laterality

Nodal involvement

Other metastatic involvement

Mention interval change if compared with previous study.

## **MRI PENIS**

Technique: Contrast enhanced MRI study was performed for penis.

Clinical details:

Comparison if any:

Findings:

**No. of lesions:**

**Lesion 1: (repeat similarly for all lesions)**

Location:

Size:

Root of penis: Involved / Not involved, Distance from root of penis if not involved

Morphology:

Corpora cavernosa involvement: If present, mention location; Crura involvement: Present / Absent;  
Ischial tuberosity involvement: Present / Absent

Corpora spongiosa involvement: If present, mention location; Penile bulb involvement: Present /  
Absent; Glans involvement: Present / Absent

Urethral involvement: If present, mention distance from prostatic apex

Scrotal involvement:

Prostate involvement:

Locoregional involvement: Pubic symphysis / rectum / urinary bladder / any other

**Nodes:** Inguinal / Pelvic

**Visualized Bones:**

**Any other significant finding:**

Impression:

Mention lesion location and locoregional involvement.

Mention nodal disease

interval change if compared with previous study.

Recommendation if any: Biopsy / Follow up / Any other investigation

## **PROSTATE MRI**

Technique: Multiparametric MRI study was performed for prostate.

Clinical details: DRE findings and biopsy findings

Tumor markers: PSA levels with trend

Comparison if any:

Findings:

**Prostate size and volume:**

**Peripheral zone / Transitional zone distinction:**

**Transitional zone: Benign Prostatic Hyperplasia (present / absent)**

**Biopsy changes if any:**

**No. of lesions: (Describe upto 4 most prominent lesions in descending order of significance)**

**Lesion 1: (repeat similarly for all lesions)**

Laterality:

Level: Base / Midgland / Apex

Site: Peripheral zone / Transitional zone distinction / Anterior fibromuscular stroma

Size:

T2 signal:

DWI with ADC value:

DCE: Type of enhancement and washout

Extracapsular bulge: Present / Absent

Extraprostatic extension (EPE): Present / Absent

If EPE present – Seminal vesicles / Urinary bladder / Neurovascular bundle / Rectum

PIRADS Category:

**Pelvic Nodes:**

**Visualised Bones:**

**Rest of the pelvic viscera:**

Impression:

Mention lesion location and PIRADS category for each lesion.

Mention extra-prostatic extension and metastatic involvement.

Mention interval change if compared with previous study.

Recommendation if any: Biopsy / Follow up / Any other investigation



**ANNEXURE -2. PATHOLOGY SYNOPTIC REPORTING FORMATS**

**RADICAL ORCHIECTOMY SPECIMENS**

**PATIENT DEMOGRAPHICS**

Name :            Age :    Sex :    Case No :

Pathology No:

Requisition No:

**Nature of specimen/procedure**

Radical/ High inguinal Orchiectomy

**GROSS FEATURES:**

**Specimen laterality**

- Right
- Left

**Tumor focality**

- Unifocal
- Multifocal

**Tumor size**

- Greatest dimension of main tumor mass: \_\_\_\_ cm
- Additional dimensions: \_\_\_\_ x \_\_\_\_ cm

*Greatest dimensions of additional tumor nodules \_\_\_\_ cm (c)*

**MICROSCOPY**

**1. Histologic subtypes (specify all subtypes present if tumour is mixed)**

**Seminoma**

- Classical Seminoma

**Non-seminomatous types**

Embryonal carcinoma

Yolk sac tumor, postpubertal type

Choriocarcinoma

Mixed germ cell tumor

- Seminoma (specify percentage): \_\_\_\_\_%

- Embryonal carcinoma (specify percentage): \_\_\_\_\_%
- Yolk sac tumor, postpubertal type (specify percentage): \_\_\_\_\_%
- Choriocarcinoma (specify percentage): \_\_\_\_\_%
- Teratoma (specify percentage): \_\_\_\_\_%

## 2. Extent of tumor ( Determines the pT stage)

- No evidence of primary tumor
- Germ cell neoplasia in situ only
- Tumor limited to testis
- Tumor invades stroma of rete testis
- Tumor invades hilar soft tissue
- Tumor invades epididymis
- Tumor invades through tunica albuginea and perforates tunica vaginalis (mesothelial layer)
- Tumor invades spermatic cord
- Tumor invades scrotum

## 3. Spermatic Cord Margin

- Cannot be assessed
- Uninvolved by tumor
- Involved by tumor

## 4. Lymphovascular Invasion

- Not identified
- Present

## 5. Regional Lymph Nodes( mostly retroperitoneal lymph node dissection)

Site / station of lymph node \_\_\_\_\_

Number of lymph nodes examined \_\_\_\_\_

Number of lymph nodes Involved: \_\_\_\_\_

Size of largest metastatic deposit (centimeters): \_\_\_\_ cm

Size of largest lymph lode Involved (centimetres): \_\_\_\_ cm

Extranodal extension

- Not identified
- Present

6. **GCNIS** – Seen or not seen

7. *Pre-Orchiectomy Serum Tumor Markers / Post-Orchiectomy Serum Tumor Markers(c)*

8. *Ancillary Studies like IHC to confirm morphology of germ cell tumor components/  
\_\_\_\_\_ (c)*

## **PENILE CANCER RESECTIONS SPECIMENS**

### **PATIENT DEMOGRAPHICS**

Name :                      Age:                                      Sex:                                      Case No:                                      Pathology No:

Requisition No:

### **MACROSCOPY**

#### **Nature of specimen/procedure**

Circumcision  Partial penectomy  Radical penectomy

Dimensions of specimen \_\_\_x\_\_\_x\_\_\_cm

#### **Tumor macroscopy**

No obvious tumour visible macroscopically

Ulcerated/ Ulceroproliferative/ Solid/ Flat/ Verrucous   

Size of tumor = \_\_\_x\_\_\_x\_\_\_ cm

Compartments involved on macroscopy

Glans                       Prepuce                       Shaft  (choose a combination if more than one involved)

Urethral involvement on macroscopy    Involved                       Not involved

#### **Margins at macroscopy**

Corporal = \_\_\_ mm                      Urethral= \_\_\_ mm                      Skin= \_\_\_ mm

### **Microscopy**

#### **1.Histologic subtypes (specify all subtypes present, if tumour is mixed)\***

Squamous carcinoma (usual type)

Basaloid squamous carcinoma

Warty/condylomatous carcinoma

Verrucous carcinoma

*\*p 16 immunohistochemistry is optional to suggest HPV vs Non HPV associated (c)*

#### **2. Grade of tumor (by worst area)**

Well differentiated (Grade 1)

Moderately differentiated (Grade 2)

Poorly differentiated (Grade 3)

Sarcomatoid areas present

**3. Maximum tumour thickness.....mm**

**4. Associated PeIN (Penile interepithelial neoplasia)** Present  Not identified

**5. Type of PeIN** Undifferentiated  Differentiated

**6. Lymphovascular invasion** Present  Not identified

**7. Perineural invasion** Present  Not identified

**8. Compartment involved microscopically (tick all that apply)**

Subepithelial invasion by tumour Yes  No

Invasion of corpus spongiosum Yes  No

Invasion of corpus cavernosum Yes  No

Urethral invasion Yes  No

Urethral margin (c) Involved  Not involved

Distance from margin.....mm ( when <5mm)

Corpus cavernosum Involved  Not involved

Distance from margin..... mm (when <5mm)

Skin cut margin Involved  Not involved

Distance from margin.....mm (when <5mm)

Deep margin in case of prepuical tumors ..... mm

**9. PeIN at margin** Yes  No  **10. Modified Inguinal lymph node dissection**

Right side inguinal nodes :	
Involved <input type="checkbox"/>	
Uninvolved <input type="checkbox"/>	
-If involved	
Total positive / Total number of nodes	
- Perinodal invasion	Seen <input type="checkbox"/>
	Not seen <input type="checkbox"/>

Left side inguinal nodes:	
Involved <input type="checkbox"/>	
Uninvolved <input type="checkbox"/>	
-If involved,	
Total positive / Total number of nodes	
- Perinodal invasion	Seen <input type="checkbox"/>
	Not seen <input type="checkbox"/>

*Size of largest lymph node involved / Size of largest metastasis (c)*

**Final Impression and stage**

Pathologic staging: pT ... pN....



- Total number of cores:
- Estimated percentage of prostatic tissue involved by tumor in each core: \_\_\_\_%

**For TURP Specimens**

Estimated percentage of prostatic tissue involved by tumor: \_\_\_\_%

- *Number of positive chips:* \_\_\_\_ (c)
- *Total number of chips:* \_\_\_\_ (c)

**5. Periprostatic Fat Invasion/Seminal Vesicle/Ejaculatory Duct Invasion (report only if identified in specimen)**

- Not identified
- Present

**6. Lymphovascular Invasion**

- Not identified
- Present

**7. Perineural Invasion**

- Not identified
- Present

*Ancillary Studies + Specify: IHC (c)*

*For basal markers p63 , HMWCK and AMACR*

**RADICAL CYSTOPROSTATECTOMY SPECIMENS**

**PATIENT DEMOGRAPHICS**

**Name:**                      **Age:**                      **Sex:**                      **Case No:**

**Pathology No:**                      **Requisition No:**

**NATURE OF SPECIMEN/PROCEDURE (POST CHEMOTHERAPY / TREATMENT NAIIVE)**

Radical cystoprostatectomy                          T

**MACROSCOPY**

*Size of specimen including size of seminal vesicle, prostate and vas (c)*

Tumour location.....

Number of tumours.....

Or no obvious tumour visible macroscopically     (Post chemotherapy effect)

Other tissues/organs included.....

Invasion into perivesical tissue (as assessed macroscopically) i.e. pT3b:

Yes     No   

Resection margins (Ureter/ Urethra)                      Not involved                          Involved Sampled in FS

Regional lymph nodes present: (Obturator, iliac)

Right

Left

Common Iliac

## MICROSCOPY

1. Histological subtype

Urothelial carcinoma

Squamous carcinoma

Adenocarcinoma

Small cell carcinoma

Other, Specify Variants of urothelial carcinoma viz. micropapillary, plasmacytoid etc need to reported in %

2. Grade of tumour

Low grade

High grade

3. Lamina propria invasion

Present

Absent

4. Detrusor muscle invasion

Present

Absent

5. Perivesical spread

Present

Absent

6. Peritoneal involvement

Present

Absent

7. Urothelial carcinoma in situ

Present

Absent

8. Lymphovascular space invasion



Present

Absent

9. Cut margins Ureter (Right and left) and Urethra---Involved / Uninvolved by tumor /CIS

10.Lymph nodes status (Obturator, iliac)

Total number of lymph nodes examined .....

Number of positive lymph nodes.....

*Size of largest focus* ..... mm (c)

Extranodal extension    Not identified                       Present

11. Status of other organs removed

Prostate Involvement    Present                       Absent

(If incidental adenocarcinoma prostate seen, report it as in radical prostatectomy)

Seminal Vesicle involvement    Present                       Absent

---

**IMPRESSION**

**Histologic type**

**pTNM classification: pT..... pN.....pM (c).....**



**Grade Group**

- Grade group 1
- Grade group 2
- Grade group 3
- Grade group 4
- Grade group 5

3. Percentage of Gleason Patterns 4 and 5 (applicable to Gleason score  $\geq 7$ ) (c)

Percentage of pattern 4: \_\_\_\_%

Percentage of pattern 5: \_\_\_\_%

**NOT REQUIRED 4. Tumour Quantitation**

Estimated approx. percentage of prostate involved by tumor: \_\_\_\_%

**5. Extra prostatic Extension (EPE)**

- Not identified
- Present, focal
- Present, nonfocal

**Location of Extraprostatic Extension** - Lateral, Apex, Base

**6. Urinary Bladder Neck Invasion**

- Not identified
- Present

**7. Seminal Vesicle Invasion**

- Not identified
- Present

**8. Margins**

Cannot be assessed

Uninvolved by invasive carcinoma

Involved by invasive carcinoma

- Limited ( $<3$  mm)
- Non-limited ( $\geq 3$  mm)

*Linear length of positive margin(s) (millimeters): \_\_\_\_\_ mm (c)*

*Focality (unifocal / multifocal): Gleason score at positive margin: Margin Positivity in Area of Extraprostatic Extension (EPE) (c)*

**9. Lymphovascular Invasion**

- Not identified
- Present

**10. Perineural Invasion**

- Not identified
- Present

**11. Regional Lymph Nodes**

Site / station of lymph node \_\_\_\_\_

Number of lymph nodes examined \_\_\_\_\_

Number of lymph nodes Involved: \_\_\_\_\_

*Size of largest metastatic deposit (centimetres):* \_\_\_\_ cm (c)

*Size of largest lymph lode Involved (centimetres):* \_\_\_\_ cm (c)

Extranodal extension

- Not identified
- Present
- Cannot be determined

**12. Path staging pT pN (AJCC 8<sup>th</sup> edition)**

**13. Ancillary Studies + Specify:** \_\_\_\_\_ (c)



## MICROSCOPY

### 1. Histological tumour type:

Clear cell renal cell carcinoma

Papillary renal cell carcinoma

                    Type 1       Type 2

Oncocytoma

Chromophobe renal cell carcinoma

Collecting duct carcinoma

Other  (specify) as per \*WHO Classification of Tumours of the Urinary System and Male Genital Organs, Fourth edition (2016) classification of renal cell tumours and the \*\*ISUP Vancouver classification of renal neoplasia

### 2. WHO/ISUP tumour grade

                    G1     G2     G3     G4

### 3. Sarcomatoid morphology

                    Not identified       Present       (if present % area)

### 4. Rhabdoid morphology

                    Not identified       Present

### 5. Tumour necrosis

                    Not identified                       Present       (if present %)

### 6. Microscopic extent of invasion

#### a) Perinephric fat invasion

                    Not identified       Present

#### b) Invasion beyond Gerota's fascia

                    Not identified       Present

#### c) Renal sinus invasion

                    Not identified                       Present

#### d) Tumour present in major veins microscopically

                    Not identified                       Present

#### e) Lymphovascular invasion

Not identified  Present

f) Tumour in the pelvicalyceal system

Not identified  Present

g) Tumour in adrenal gland (if present)

Not involved  Present, contiguous extension  Present, metastasis

### 7) Lymph nodes status

Total number of lymph nodes examined .....

Number of positive lymph nodes.....

Size of largest focus ..... mm (c)

Extra nodal extension Not identified  Present

### 8. Resection margins

Renal vein cut margin

Renal artery cut margin

Ureteric cut margin

Parenchymal cut margin (in case of nephron sparing surgery)

### 9. Co-existing pathology in non-neoplastic kidney

#### IMPRESSION

Histologic type

Tumour stage : pT..... pN..... pM..... (M1 only, if applicable)

\*World Health Organization WHO

\*\*International Society of Urological Pathology ISUP

## **TRANSURETHRAL RESECTION OF URINARY BLADDER/ URETERIC RESECTIONS**

### **SPECIMENS**

#### **Patient demographics**

Name :

Age:

Sex:

Case No:

Pathology No:

Requisition No:

**Procedure – TURBT/TUR biopsy/ Transurethral resection of ureteric tumour**

#### **Site of the specimen**

Ureter

Bladder

#### **Gross Macroscopy**

Single tissue bit

Multiple Tissue bits aggregating to \_\_\_x\_\_\_x\_\_\_ cm

#### **Tissue submitted**

Entirely

Partly

#### **Microscopy**

1. Histological subtype
  - Urothelial carcinoma
  - Squamous carcinoma
  - Adenocarcinoma
  - Small cell carcinoma
  - Variant of Urothelial carcinoma viz. micropapillary, plasmacytoid etc needs to reported in %
  - Other, specify
2. Grade of tumour
  - PUNLMP
  - Low grade
  - High grade
3. Lamina propria invasion
  - Present
  - Absent
4. Detrusor muscle/Muscularis propria
  - Included
  - Not included
  - Indeterminate



5. If Muscle included, then invasion
  - Present
  - Absent
6. Report Urothelial carcinoma in situ, if present
7. Report lymphovascular space invasion, if present

**Impression**

Grade and type of tumor

T stage (AJCC 8th edition) =pT.....