



# Bladder cancer: diagnosis and management

NICE guideline

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# Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

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This guideline is the basis of QS106.

### Overview

This guideline covers diagnosing and managing bladder cancer in adults aged 18 and over referred from primary care with suspected bladder cancer, and those with newly diagnosed or recurrent bladder (urothelial carcinoma, adenocarcinoma, squamous-cell carcinoma or small-cell carcinoma) or urethral cancer.

For recommendations on when to refer people from primary care to a specialist, see NICE's guideline on recognition and referral for suspected cancer.

### Who is it for?

- Healthcare professionals
- · Commissioners and providers
- Adults with bladder cancer and their families and carers

### Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <a href="NICE's information on making decisions about your care">NICE's information on making decisions about your care</a>.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

Healthcare professionals and social care practitioners should follow our general guidelines for people delivering care:

- Care of dying adults in the last days of life
- End of life care for adults: service delivery
- Improving outcomes in urological cancers
- Improving supportive and palliative care for adults with cancer
- Overweight and obesity management
- Patient experience in adult NHS services
- People's experience in adult social care services
- Shared decision making
- Tobacco: preventing uptake, promoting quitting and treating dependence
- Workplace health

# 1.1 Information and support for adults with bladder cancer

- Offer clinical nurse specialist support to adults with bladder cancer and give them the clinical nurse specialist's contact details.
- 1.1.2 Ensure that the clinical nurse specialist:
  - acts as the key worker to address the person's information and care needs
  - has experience and training in bladder cancer care.
- 1.1.3 Use a holistic needs assessment to identify an individualised package of information and support for adults with bladder cancer and, if they wish, their partners, families or carers, at key points in their care such as:
  - when they are first diagnosed
  - after they have had their first treatment
  - if their bladder cancer recurs or progresses
  - if their treatment is changed
  - if palliative or end of life care is being discussed.
- 1.1.4 When carrying out a holistic needs assessment, recognise that many of the symptoms, investigations and treatments for bladder cancer affect the urogenital organs and may be distressing and intrusive. Discuss with the person:
  - the potential complications of intrusive procedures, including urinary retention, urinary infection, pain, bleeding or need for a catheter
  - the impact of treatment on their sexual health and body image, including how to find relevant support and information
  - stopping smoking (see NICE's guideline on tobacco: preventing uptake, promoting quitting and treating dependence).
- 1.1.5 Offer adults with bladder cancer and, if they wish, their partners, families or

- carers, opportunities to have discussions at any stage during their treatment and care with other people with bladder cancer who have had similar treatments, including people who have had a urinary stoma or continent urinary diversion.
- 1.1.6 Trusts, health boards and other relevant healthcare providers should consider conducting annual bladder cancer patient satisfaction surveys developed by their urology multidisciplinary team and adults with bladder cancer, and use the results to guide a programme of quality improvement.

### 1.2 Diagnosing and staging bladder cancer

### Diagnosis

- 1.2.1 Do not substitute urinary biomarkers for cystoscopy to investigate suspected bladder cancer or for follow-up after treatment for bladder cancer, except in the context of a clinical research study.
- 1.2.2 Consider CT or MRI staging before transurethral resection of bladder tumour (TURBT) if muscle-invasive bladder cancer is suspected at cystoscopy.
- 1.2.3 Offer white-light-guided TURBT with one of photodynamic diagnosis, narrow-band imaging, cytology or a urinary biomarker test (such as UroVysion using fluorescence in-situ hybridization [FISH], ImmunoCyt or a nuclear matrix protein 22 [NMP22] test) to adults with suspected bladder cancer. This should be carried out or supervised by a urologist experienced in TURBT.
- 1.2.4 Obtain detrusor muscle during TURBT.
- Do not take random biopsies of normal-looking urothelium during TURBT unless there is a specific clinical indication (for example, investigation of positive cytology not otherwise explained).
- 1.2.6 Record the size and number of tumours during TURBT.
- 1.2.7 Offer adults with suspected bladder cancer a single dose of intravesical

mitomycin C given at the same time as the first TURBT.

### Staging

- 1.2.8 Consider further TURBT within 6 weeks if the first specimen does not include detrusor muscle.
- 1.2.9 Offer CT or MRI staging to adults diagnosed with muscle-invasive bladder cancer or <a href="https://niches.no-muscle-invasive-bladder-cancer">high-risk non-muscle-invasive-bladder cancer</a> that is being assessed for radical treatment.
- 1.2.10 Consider CT urography, carried out with other planned CT imaging if possible, to detect upper tract involvement in adults with new or recurrent high-risk non-muscle-invasive or muscle-invasive bladder cancer.
- 1.2.11 Consider CT of the thorax, carried out with other planned CT imaging if possible, to detect thoracic malignancy in adults with muscle-invasive bladder cancer.
- 1.2.12 Consider fluorodeoxyglucose positron emission tomography (FDG PET)-CT for adults with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer before radical treatment if:
  - there are indeterminate findings on CT or MRI, or
  - a high risk of metastatic disease (for example, T3b disease).

### 1.3 Treating non-muscle-invasive bladder cancer

### Prognostic markers and risk classification

1.3.1 Ensure that for adults with non-muscle-invasive bladder cancer all of the following are recorded and used to guide discussions, both within multidisciplinary team meetings and with the person, about prognosis and treatment options:

- recurrence history
- size and number of cancers
- histological type, grade, stage and presence (or absence) of flat urothelium, detrusor muscle (muscularis propria), and carcinoma in situ
- the risk category of the person's cancer
- predicted risk of recurrence and progression, estimated using a risk prediction tool.

### Low-risk non-muscle-invasive bladder cancer

1.3.2 For the treatment of <u>low-risk non-muscle-invasive bladder cancer</u>, see also recommendations 1.2.3 to 1.2.8 on the use of white-light-guided TURBT and intravesical mitomycin C in the <u>sections on diagnosing and staging bladder</u> cancer.

#### Intermediate-risk non-muscle-invasive bladder cancer

- 1.3.3 Offer adults with newly diagnosed <u>intermediate-risk non-muscle-invasive bladder</u> cancer a course of at least 6 doses of intravesical mitomycin C.
- 1.3.4 If intermediate-risk non-muscle-invasive bladder cancer recurs after a course of intravesical mitomycin C, refer the person's care to a specialist urology multidisciplinary team.

### High-risk non-muscle-invasive bladder cancer

- 1.3.5 If the first TURBT shows <u>high-risk non-muscle-invasive bladder cancer</u>, offer another TURBT as soon as possible and no later than 6 weeks after the first resection.
- 1.3.6 Offer the choice of intravesical BCG (Bacille Calmette-Guérin) or radical

cystectomy to adults with high-risk non-muscle-invasive bladder cancer.

1.3.7 Involve the clinical nurse specialist and a urologist who performs both intravesical BCG and radical cystectomy in discussions with the person about the choice of treatment.

#### Intravesical BCG

- 1.3.8 Offer induction and maintenance intravesical BCG to adults having treatment with intravesical BCG.
- 1.3.9 If induction BCG fails (because it is not tolerated, or bladder cancer persists or recurs after treatment with BCG), refer the person's care to a specialist urology multidisciplinary team.
- 1.3.10 For adults in whom induction BCG has failed, the specialist urology multidisciplinary team should assess the suitability of radical cystectomy, or further intravesical therapy if radical cystectomy is unsuitable or declined by the person, or if the bladder cancer that recurs is intermediate or low risk.

#### Radical cystectomy

1.3.11 See the <u>section on radical cystectomy</u> for adults who have chosen this procedure.

#### Recurrent non-muscle-invasive bladder cancer

- 1.3.12 Consider fulguration without biopsy for adults with recurrent non-muscle-invasive bladder cancer if they have all of the following:
  - no previous bladder cancer that was intermediate or high risk
  - a disease-free interval of at least 6 months
  - solitary papillary recurrence

a tumour diameter of 3 mm or less.

### Managing side effects of treatment

- 1.3.13 Do not offer primary prophylaxis to prevent BCG-related bladder toxicity except as part of a clinical trial.
- 1.3.14 Seek advice from a specialist urology multidisciplinary team if symptoms of bladder toxicity after BCG cannot be controlled with antispasmodics or non-opiate analgesia and other causes have been excluded by cystoscopy.

### 1.4 Follow-up after treatment for non-muscleinvasive bladder cancer

- 1.4.1 Refer people urgently to urological services if they have haematuria or other urinary symptoms and a history of non-muscle-invasive bladder cancer.
- 1.4.2 See recommendation 1.2.1 on the use of urinary biomarkers for follow up after treatment for bladder cancer in the section on diagnosis.

#### Low-risk non-muscle-invasive bladder cancer

- 1.4.3 Offer adults with <u>low-risk non-muscle-invasive bladder cancer</u> cystoscopic follow-up 3 months and 12 months after diagnosis.
- 1.4.4 Do not use urinary biomarkers or cytology in addition to cystoscopy for follow-up after treatment for low-risk bladder cancer.
- 1.4.5 Discharge to primary care adults who have had low-risk non-muscle-invasive bladder cancer and who have no recurrence of the bladder cancer within 12 months.
- 1.4.6 Do not offer routine urinary cytology or prolonged cystoscopic follow-up after

12 months for adults with low-risk non-muscle-invasive bladder cancer.

#### Intermediate-risk non-muscle-invasive bladder cancer

- 1.4.7 Offer adults with <u>intermediate-risk non-muscle-invasive bladder cancer</u> cystoscopic follow-up at 3, 9 and 18 months, and once a year thereafter.
- 1.4.8 Consider discharging adults who have had intermediate-risk non-muscle-invasive bladder cancer to primary care after 5 years of disease-free follow-up.

### High-risk non-muscle-invasive bladder cancer

- 1.4.9 Offer adults with <u>high-risk non-muscle-invasive bladder cancer</u> cystoscopic follow-up:
  - every 3 months for the first 2 years then
  - every 6 months for the next 2 years then
  - once a year thereafter.
- 1.4.10 For adults who have had radical cystectomy for high-risk non-muscle-invasive bladder cancer, follow recommendations 1.6.1 and 1.6.2 in the <u>section on follow-up after treatment for muscle-invasive bladder cancer</u>.

### 1.5 Treating muscle-invasive bladder cancer

1.5.1 Ensure that a specialist urology multidisciplinary team reviews all cases of muscle-invasive bladder cancer, including adenocarcinoma, squamous cell carcinoma and neuroendocrine carcinoma, and that the review includes histopathology, imaging and discussion of treatment options.

# Neoadjuvant chemotherapy for newly diagnosed muscle-invasive urothelial bladder cancer

- 1.5.2 Offer neoadjuvant chemotherapy using a cisplatin combination regimen before radical cystectomy or radical radiotherapy to adults with newly diagnosed muscle-invasive urothelial bladder cancer for whom cisplatin-based chemotherapy is suitable.
- 1.5.3 Involve an oncologist who treats bladder cancer in discussions with the person about the risks and benefits of neoadjuvant chemotherapy using a cisplatin combination regimen before radical cystectomy, or radical radiotherapy.

### Radical therapy for muscle-invasive urothelial bladder cancer

- 1.5.4 Offer a choice of radical cystectomy or radiotherapy with a radiosensitiser to adults with muscle-invasive urothelial bladder cancer for whom radical therapy is suitable.
- 1.5.5 Involve a urologist who performs radical cystectomy, a clinical oncologist and a clinical nurse specialist in discussions with the person about the choice of treatment.
- 1.5.6 When discussing the choice of treatment, cover the:
  - prognosis with or without treatment
  - limited evidence about whether surgery or radiotherapy with a radiosensitiser is the most effective cancer treatment
  - benefits and risks of surgery and radiotherapy with a radiosensitiser, including the impact on sexual and bowel function and the risk of death as a result of the treatment.

### **Radical cystectomy**

1.5.7 Offer adults who have chosen radical cystectomy a urinary stoma, or a continent

- urinary diversion (bladder substitution or a catheterisable reservoir) if there are no strong contraindications to continent urinary diversion such as cognitive impairment, impaired renal function or significant bowel disease.
- 1.5.8 Members of the specialist urology multidisciplinary team (including the bladder cancer specialist urological surgeon, stoma care nurse and clinical nurse specialist) should discuss with the person whether to have a urinary stoma or continent urinary diversion.
- 1.5.9 Offer adults with bladder cancer and, if they wish, their partners, families or carers, opportunities to have discussions with a stoma care nurse before and after radical cystectomy as needed.

# Adjuvant systemic anticancer therapy after radical cystectomy for muscle-invasive or lymph-node-positive urothelial bladder cancer

- 1.5.10 Consider adjuvant cisplatin combination chemotherapy after radical cystectomy for adults with a diagnosis of muscle-invasive or lymph-node-positive urothelial bladder cancer for whom neoadjuvant chemotherapy was not suitable (because muscle invasion was not shown on biopsies before cystectomy).
- 1.5.11 Nivolumab is recommended as an option in NICE technology appraisal guidance for adjuvant treatment of muscle-invasive urothelial cancer at high risk of recurrence after radical resection in adults whose tumours express PD-L1 at a level of 1% or more and for whom platinum-based chemotherapy is unsuitable. For full details, see the guidance on nivolumab (TA817, 2022).
- 1.5.12 Involve an oncologist who treats bladder cancer in discussions with the person about the risks and benefits of adjuvant systemic anticancer therapy after radical cystectomy.

### Radical radiotherapy

1.5.13 Use a radiosensitiser (such as mitomycin in combination with fluorouracil [5-FU] or carbogen in combination with nicotinamide) when giving radical radiotherapy

(for example, 64 Gy in 32 fractions over 6.5 weeks or 55 Gy in 20 fractions over 4 weeks) for muscle-invasive urothelial bladder cancer.

In February 2015, this was an off-label use of mitomycin in combination with fluorouracil and carbogen in combination with nicotinamide. See <u>NICE's</u> information on prescribing medicines.

### Managing side effects of radiotherapy treatment

1.5.14 Seek advice from a specialist urology multidisciplinary team if symptoms of bladder toxicity after radiotherapy cannot be controlled with antispasmodics or non-opiate analgesia and other causes have been excluded by cystoscopy.

# 1.6 Follow-up after treatment for muscle-invasive bladder cancer

- 1.6.1 After radical cystectomy consider using a follow-up protocol that consists of:
  - monitoring of the upper tracts for hydronephrosis, stones and cancer using imaging and glomerular filtration rate (GFR) estimation at least annually and
  - monitoring for local and distant recurrence using CT of the abdomen, pelvis and chest, carried out together with other planned CT imaging if possible, 6, 12 and 24 months after radical cystectomy and
  - monitoring for metabolic acidosis and B12 and folate deficiency at least annually and
  - for those with a defunctioned urethra, urethral washing for cytology and/or urethroscopy annually for 5 years to detect urethral recurrence.
- 1.6.2 After radical radiotherapy consider using a follow-up protocol that includes all of the following:
  - rigid cystoscopy 3 months after radiotherapy has been completed, followed by either rigid or flexible cystoscopy:

- every 3 months for the first 2 years then
- every 6 months for the next 2 years then
- every year thereafter, according to clinical judgement and the person's preference
- upper-tract imaging every year for 5 years
- monitoring for local and distant recurrence using CT of the abdomen, pelvis and chest, carried out with other planned CT imaging if possible, 6, 12 and 24 months after radical radiotherapy has finished.
- 1.6.3 See recommendation 1.2.1 on the use of urinary biomarkers for follow-up after treatment for bladder cancer in the section on diagnosis.

# 1.7 Managing locally advanced or metastatic muscle-invasive bladder cancer

### First-line systemic anticancer therapy

- 1.7.1 Offer a cisplatin-based chemotherapy regimen (such as cisplatin in combination with gemcitabine, or accelerated [high-dose] methotrexate, vinblastine, doxorubicin and cisplatin [MVAC] in combination with granulocyte-colony stimulating factor [G-CSF]) to adults with locally advanced or metastatic urothelial bladder cancer who are:
  - otherwise physically fit (have an <u>Eastern Cooperative Oncology Group</u> [ECOG] performance status of 0 or 1) and
  - have adequate renal function (typically defined as a glomerular filtration rate [GFR] of 60 ml/min/1.73 m<sup>2</sup> or more).
- 1.7.2 Offer carboplatin in combination with gemcitabine to adults with locally advanced or metastatic urothelial bladder cancer with an ECOG performance status of 0 to 2 if a cisplatin-based chemotherapy regimen is unsuitable, for example,

because of ECOG performance status, inadequate renal function (typically defined as a GFR of less than 60 ml/min/1.73 m<sup>2</sup>) or comorbidity.

In September 2025 this was an off-label use of carboplatin in combination with gemcitabine. See NICE's information on prescribing medicines.

- 1.7.3 Enfortumab vedotin with pembrolizumab is recommended as an option in NICE technology appraisal guidance for untreated unresectable or metastatic urothelial cancer in adults when platinum-based chemotherapy is suitable. For full details, see the guidance on enfortumab (TA1097, 2025).
- 1.7.4 Atezolizumab is recommended as an option in NICE technology appraisal guidance for adults with untreated locally advanced or metastatic urothelial cancer whose tumours express PD-L1 at a level of 5% or more and for whom cisplatin-containing chemotherapy is unsuitable. For full details, see the guidance on atezolizumab (TA739, 2021).
- 1.7.5 For adults having first-line systemic anticancer therapy for locally advanced or metastatic bladder cancer:
  - carry out regular clinical and radiological monitoring and
  - actively manage symptoms of disease and treatment-related toxicity and
  - stop first-line systemic anticancer therapy if there is excessive toxicity or disease progression.

# Maintenance systemic anticancer therapy after platinum-based chemotherapy

1.7.6 Avelumab is recommended as an option in NICE technology appraisal guidance for maintenance treatment of locally advanced or metastatic urothelial cancer in adults that has not progressed after platinum-based chemotherapy, only if avelumab is stopped at 5 years of uninterrupted treatment or earlier if the disease progresses. For full details, see the guidance on avelumab (TA788, 2022).

### Second-line systemic anticancer therapy

- 1.7.7 Consider second-line chemotherapy with gemcitabine in combination with cisplatin, or accelerated (high-dose) MVAC in combination with G-CSF for adults with incurable locally advanced or metastatic urothelial bladder cancer whose condition has progressed after first-line systemic anticancer therapy if:
  - their renal function is adequate (typically defined as a GFR of 60 ml/min/ 1.73 m<sup>2</sup> or more) and
  - they are otherwise physically fit (have an ECOG performance status of 0 or 1).
- 1.7.8 Consider second-line chemotherapy with carboplatin in combination with paclitaxel or gemcitabine in combination with paclitaxel for adults with incurable locally advanced or metastatic urothelial bladder cancer for whom cisplatin-based chemotherapy is not suitable, or who choose not to have it.
  - In September 2025 this was an off-label use of carboplatin in combination with gemcitabine and gemcitabine in combination with paclitaxel. See <u>NICE's</u> information on prescribing medicines.
- 1.7.9 Atezolizumab is recommended as an option in NICE technology appraisal guidance for treating locally advanced or metastatic urothelial cancer in adults after platinum-containing chemotherapy, only if atezolizumab is stopped at 2 years of uninterrupted treatment or earlier if the disease progresses. For full details, see the guidance on atezolizumab (TA525, 2018).
- 1.7.10 Erdafitinib is recommended as an option in NICE technology appraisal guidance for treating unresectable or metastatic urothelial cancer with susceptible FGFR3 genetic alterations in adults after at least 1 line of treatment for unresectable or metastatic cancer that included a PD-1 or PD-L1 inhibitor. For full details, see the guidance on erdafitinib (TA1062, 2025).
- 1.7.11 For adults having second-line systemic anticancer therapy for locally advanced or metastatic bladder cancer:
  - · carry out regular clinical and radiological monitoring and

- actively manage symptoms of disease and treatment-related toxicity and
- stop second-line systemic anticancer therapy if there is excessive toxicity or disease progression.
- 1.7.12 For medicines not recommended in NICE technology appraisal guidance for treating locally advanced or metastatic urothelial cancer after platinum-containing chemotherapy, see the guidance on:
  - pembrolizumab (TA692, 2021)
  - nivolumab (TA530, 2018)
  - vinflunine (TA272, 2013).

# Neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours

- 1.7.13 For NTRK inhibitors recommended as options in NICE technology appraisal guidance through the Cancer Drugs Fund for treating locally advanced or metastatic NTRK fusion-positive solid tumours when there are no other satisfactory treatment options, see the guidance on:
  - entrectinib (TA644, August 2020)
  - larotrectinib (TA630, May 2020).

# Managing symptoms of locally advanced or metastatic bladder cancer

### Bladder symptoms

1.7.14 Offer palliative hypofractionated radiotherapy to adults with symptoms of haematuria, dysuria, urinary frequency or nocturia caused by advanced bladder cancer that is unsuitable for potentially curative treatment.

#### Loin pain and symptoms of renal failure

- 1.7.15 Consider percutaneous nephrostomy or retrograde stenting (if technically feasible) for adults with locally advanced or metastatic bladder cancer and ureteric obstruction who need treatment to relieve pain, treat acute kidney injury or improve renal function before further treatment.
- 1.7.16 Discuss options for people with bladder cancer and ureteric obstruction with a specialist urology multidisciplinary team, if:
  - facilities for percutaneous nephrostomy or retrograde stenting are not available at the local hospital, or
  - these procedures are unsuccessful.

#### Intractable bleeding

- 1.7.17 Evaluate the cause of intractable bleeding with the local urology team.
- 1.7.18 Consider hypofractionated radiotherapy or embolisation for adults with intractable bleeding caused by incurable bladder cancer.
- 1.7.19 Discuss further management with a specialist urology multidisciplinary team, if:
  - the person has intractable bleeding caused by bladder cancer, and
  - radiotherapy or embolisation are not suitable treatments.

#### Pelvic pain

- 1.7.20 Evaluate the cause of pelvic pain with the local urology team.
- 1.7.21 Consider, in addition to best supportive care, 1 or more of the following to treat pelvic pain caused by incurable bladder cancer:
  - hypofractionated radiotherapy if the person has not had pelvic radiotherapy

- nerve block
- palliative chemotherapy.

# 1.8 Specialist palliative care for adults with incurable bladder cancer

- 1.8.1 Offer adults with symptomatic incurable bladder cancer access to a urological team with the full range of options for managing symptoms.
- 1.8.2 A member of the treating team should explain to adults with incurable bladder cancer that their disease cannot be cured and refer them to the urology multidisciplinary team.
- 1.8.3 Tell the primary care team that the person has been given a diagnosis of incurable bladder cancer within 24 hours of telling the person.
- 1.8.4 A member of the urology multidisciplinary team should discuss the prognosis and management options with adults with incurable bladder cancer.
- 1.8.5 Discuss palliative care services with adults with incurable bladder cancer and, if needed and they agree, refer them to a specialist palliative care team (for more information, see recommendation 1.1.3 on holistic needs assessment in the section on information and support, and NICE's guidelines on improving supportive and palliative care for adults with cancer and improving outcomes in urological cancers).

## Terms used in this guideline

### Low risk non-muscle-invasive bladder cancer

Urothelial cancer with any of:

solitary pTaG1 with a diameter of less than 3 cm

- solitary pTaG2 (low grade) with a diameter of less than 3 cm
- any papillary urothelial neoplasm of low malignant potential.

#### Intermediate risk non-muscle-invasive bladder cancer

Urothelial cancer that is not low risk or high risk, including:

- solitary pTaG1 with a diameter of more than 3 cm
- multifocal pTaG1
- solitary pTaG2 (low grade) with a diameter of more than 3 cm
- multifocal pTaG2 (low grade)
- pTaG2 (high grade)
- any pTaG2 (grade not further specified)
- any low-risk non-muscle-invasive bladder cancer recurring within 12 months of last tumour occurrence.

### High-risk non-muscle-invasive bladder cancer

Urothelial cancer with any of:

- pTaG3
- pT1G2
- pT1G3
- pTis (Cis)
- aggressive variants of urothelial carcinoma, for example micropapillary or nested variants.

### Recommendations for research

The guideline committee has made the following recommendations for research. The guideline committee's full set of recommendations for research are detailed in the  $\underline{\text{full}}$  guideline.

### 1 Patient satisfaction

What are the causative and contributory factors underlying the persistently very low levels of reported patient satisfaction for bladder cancer?

### Why this is important

The urological cancers grouping (which includes bladder cancer but excludes prostate cancer) has consistently appeared near the bottom of the table of patient satisfaction comparisons of all cancer types in national patient experience surveys. Prostate cancer (which is also managed in urological services) is recorded separately and has continued to appear near the top of the tables.

It is uncertain why this is the case, except that there is now an accepted link between the level of clinical nurse specialist allocation, information and support provision and patient satisfaction. The urological cancers grouping has the lowest level of clinical nurse specialist allocation in comparison with all other cancer types or groupings (including prostate cancer). The prolonged pattern of intrusive procedures that dominate investigation, treatment and follow-up regimens for bladder cancer may also contribute to this position. Additionally, there is concern that adults with bladder cancer at or near the end of life, who are by that stage often quite frail and elderly, may not always have access to the full range of palliative and urological support and may, at times, be treated in general wards in hospital and experience significant symptoms of pain and bleeding (haematuria).

To explore this research question bladder cancer patients need to be identified separately from the generic group of urological cancer patients in nationally collected data sets.

### 2 BCG or primary cystectomy in high-risk non-

### muscle-invasive bladder cancer

Is primary radical cystectomy more effective than primary intravesical BCG in <u>high-risk</u> non-muscle-invasive bladder cancer, in terms of quality of life and cancer-specific outcomes?

### Why this is important

Options for adults with high-risk non-muscle-invasive bladder cancer include cystoscopy surveillance, BCG immunotherapy or radical surgery. To date, these have not been directly compared across the same population to understand their relative benefits.

Bladder-sparing approaches avoid major surgery, but have a greater risk of cancer progression. The potential advantage of bladder-sparing approaches compared with cystectomy in maintaining quality of life may be offset by continuing concern about cancer progression and morbidity from treatment. Primary cystectomy may improve survival; however, it has high short-term risks and life-changing consequences. It will be overtreatment for those adults whose cancer would not have progressed.

# 3 Follow-up of high-risk non-muscle-invasive bladder cancer

In adults with high-risk non-muscle-invasive bladder cancer, are these follow-up regimens equally effective in terms of identification of progression, cost effectiveness and health-related quality of life?

- Cystoscopic follow-up at 3, 6, 12, 18, 24, 36 and 48 months, and then annually, interspersed with non-invasive urinary tests.
- Cystoscopic follow-up at 3, 6, 9, 12, 15, 18, 21, 24, 30, 36, 42 and 48 months, and then annually thereafter.

### Why this is important

Cystoscopy is currently the standard of care for follow-up of adults with high-risk non-muscle-invasive bladder cancer. Regular cystoscopy may be associated with anxiety, procedural discomfort to the person and significant costs to the NHS.

Urine tests based on a variety of technologies (including cytology, fluorescence in-situ hybridization [FISH] and proteomic platforms) can detect high-grade recurrence, raising the possibility that 1 or more of these tests could be used to reduce the frequency of cystoscopy. This could improve acceptability to patients and reduce costs to the NHS without increasing the risk of disease progression.

There is a lack of evidence on the optimal frequency of follow-up and whether the frequency of cystoscopy follow-up can safely be reduced by substitution of urinary tests.

### 4 Biomarkers for treatment selection

In patients with muscle-invasive bladder cancer suitable for radical treatment, does the use of biomarkers enable patients to select more effective treatment, and improve their outcomes, compared with treatment selected without biomarkers?

### Why this is important

Response to surgery or radiotherapy is difficult to predict for individuals. There is variation not only in the cure rates for patients with muscle-invasive bladder cancer treated with either surgery or radiotherapy, but also in the side effects experienced during and after treatment. The usefulness of current biomarkers in predicting treatment outcomes for individual patients has not been clearly established. Currently treatment decisions are based on patient-related factors, and patient and clinician preference. Research into biomarkers that can predict the response of the patient's muscle-invasive bladder cancer to either radiotherapy or surgery could help individual patients and clinicians decide which treatment is more suitable and is considered an important step toward individualised treatment.

### 5 Follow-up after radical treatment for organconfined muscle-invasive bladder cancer

Is symptom-based review as effective as scheduled follow-up for adults treated with radical cystectomy or radical radiotherapy for organ-confined, muscle-invasive bladder cancer? Outcomes of interest are overall survival, health-related quality of life, resource use and cost.

### Why this is important

Standard care after treatment for organ-confined, muscle-invasive bladder cancer is scheduled follow-up at intervals set out by the treating team. Although this can be reassuring for both the patient and the treating team, it is not known whether scheduled follow-up offers clinical benefit compared with symptom-based review, which is increasingly used for adults with other cancers. Moreover, there are significant costs associated with follow-up. The current evidence about follow-up is confined to cystectomy. There is no evidence concerning follow-up after radiotherapy. In addition, the evidence on radiological follow-up uses mainly outdated imaging techniques.

# Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the <u>NICE</u> topic page on bladder cancer.

For full details of the evidence and the guideline committee's discussions, see the <u>full</u> <u>guideline and evidence review</u>. You can also find information about <u>how the guideline was developed</u>, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

# **Update information**

#### Minor changes since publication

September 2025: We added links to relevant technology appraisal guidance in the sections on treating muscle-invasive bladder cancer and managing locally advanced or metastatic muscle-invasive bladder cancer. We also simplified the guideline by removing recommendations on general principles of care that are covered in other NICE guidelines.

January 2022: Minor changes to update links.

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