EAU GUIDELINES ON NON-MUSCLE-INVASIVE (TaT1, CIS) BLADDER CANCER

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Epidemiology and aetiology

Bladder cancer (BC) is the sixth most commonly diagnosed cancer in the male population worldwide, and it is ninth when both sexes are considered. The worldwide age-standardised incidence rate (per 100,000 person/years) is 9.3 in males and 2.4 in females. Several risk factors connected with the risk of BC diagnosis have been identified. Tobacco smoking is the most important risk factor for BC, accounting for approximately 50% of cases.

Staging and classification systems

The 2025 Tumour, Node, Metastasis (TNM) Classification is used for staging (Table 1). For grading, both the older 1973 (which distinguish between grade 1 [G1], grade 2 [G2] and grade 3 [G3] categories) and the newer 2004/2022 World Health Organization (WHO) grading classifications (that categorises BC into papillary urothelial neoplasm of low malignant potential [PUNLMP], non-invasive papillary carcinoma low

grade [LG] and high grade [HG]) can be used, although WHO currently supports the 2004/2022 grading classification. While the two grading systems are prognostic for progression, a 3-tier combination (LG/G1-G2, HG/G2 & HG/G3) of both proved to be superior to either classification system alone.

Table 1: TNM Classification 2025

T - Primary tumour	
TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Ta	Non-invasive papillary carcinoma
Tis	Carcinoma *in situ*: 'flat tumour'
T1	Tumour invades subepithelial connective tissue
T2	Tumour invades muscle
T2a	Tumour invades superficial muscle (inner half)
T2b	Tumour invades deep muscle (outer half)
T3	Tumour invades perivesical tissue
T3a	Microscopically
T3b	Macroscopically (extravesical mass)
T4	Tumour invades any of the following: prostate stroma, seminal vesicles, uterus, vagina pelvic wall, abdominal wall
T4a	Tumour invades prostate stroma, seminal vesicles, uterus or vagina
T4b	Tumour invades pelvic wall or abdominal wall
N - Regional lymph nodes	
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single lymph node in the true pelvis (hypogastric, obturator, external iliac or presacral)

N2	Metastasis in multiple regional lymph nodes in the true pelvis (hypogastric, obturator,external iliac or presacral)	
N3	Metastasis in common iliac lymph node(s)	
M - Distant metastasis		
M0	No distant metastasis	
	M1a	Non-regional lymph nodes
	M1b	Other distant metastases

Types of carcinoma *in situ*

Carcinoma *in situ* (CIS) is an intra-epithelial, high-grade, non-invasive urothelial carcinoma (UC), and may be classified into the following clinical types:

- Primary: isolated CIS with no previous or concurrent papillary tumours and no previous CIS;
- Secondary: CIS detected during follow-up of patients with a previous tumour that was not CIS; or
- Concurrent: CIS in the presence of any other urothelial tumour in the bladder.

Subtypes of urothelial carcinoma and lymphovascular invasion

Most subtypes of UC (micropapillary, plasmacytoid, sarcomatoid) have a worse prognosis than pure HG UC. The presence of lymphovascular invasion (LVI) in transurethral resection of the bladder (TURB) specimens is associated with worse prognosis.

Recommendations for bladder cancer classification	Strength rating
Use the 2025 Tumour, Node, Metastasis Classification system for classification of the depth of tumour invasion (staging).	Strong
Use the 2004/2022 World Health Organization grading classification system. If available, use a hybrid system based on both the 1973 and 2004/2022 systems.	Strong
Do not use the term 'superficial' bladder cancer.	Strong

Diagnostic evaluation

A focused patient history is mandatory. Haematuria is the most common finding. Carcinoma *in situ* might be suspected in patients with lower urinary tract symptoms, especially voiding symptoms.

Recommendations for the primary assessment of non-muscle-invasive bladder cancer	Strength rating
Take a patient history, focusing on urinary tract symptoms and haematuria.	Strong
Use renal and bladder ultrasound and/or computed tomography (CT) urography during the initial work-up in patients with haematuria.	Strong
Once a bladder tumour has been detected, perform a CT urography in selected cases (e.g. tumours located in the trigone, or multiple- or high-risk tumours).	Strong

If a magnetic resonance imaging is performed for local staging of bladder cancer (BC), it should be done before transurethral resection of bladder tumour.	Strong
Perform cystoscopy, with or without biopsy confirmation, in patients with symptoms suggestive of bladder cancer. It cannot be replaced by cytology or by any other non-invasive test.	Strong
Use a flexible cystoscope, if available, in both males and females. In male patients, apply irrigation 'bag squeeze' to decrease procedural pain when passing the proximal urethra.	Strong
Describe all macroscopic features of the tumour (site, size, number and appearance) and mucosal abnormalities during cystoscopy. Use a bladder diagram.	Strong
Use voided urine cytology as an adjunct to cystoscopy to detect high-grade tumour.	Strong
Perform cytology on at least 25 mL fresh urine or urine with adequate fixation. First morning urine is not suitable due to the frequent presence of cytolysis.	Strong
Use the Paris System 2nd Edn., for cytology reporting.	Strong

Papillary (TaT1) tumours

The diagnosis of papillary BC ultimately depends on cystoscopic examination of the bladder and histological evaluation of the tissue resected during TURB. Transurethral resection of the bladder is a crucial procedure in the diagnosis and treatment of TaT1 tumours and should be performed systematically in individual steps. A complete resection,

performed by either fractioned or *en-bloc* technique, is essential to achieve a good prognosis.
The technique selected depends on the size of the lesion, its location and experience of the surgeon. In selected cases, due to the risk of tumour persistence and understaging after initial TURB, a second resection (2nd TURB) is recommended.

Carcinoma *in situ*

Carcinoma *in situ* is diagnosed by a combination of cystoscopy, urine cytology and histological evaluation of bladder biopsies taken from suspicious areas, or as mapping biopsies from normal-looking mucosa (for details, please consult the extended Non-muscle-invasive Bladder Cancer [NMIBC] Guidelines). Carcinoma *in situ* cannot be eradicated by TURB, and further treatment is mandatory.

Recommendations for transurethral resection of the bladder (TURB), biopsies and pathology report	**Strength rating**
Perform TURB followed by pathology investigation of the obtained specimen(s) as a diagnostic procedure and initial treatment step in patients suspected of having bladder cancer.	Strong

Perform TURB systematically in individual steps: • bimanual palpation under anaesthesia before starting the procedure and at the end; • insertion of the resectoscope, under visual control with inspection of the whole urethra; • thorough inspection of the whole urothelial lining of the bladder; • biopsy from the prostatic urethra (if indicated); • cold-cup bladder biopsies (if indicated); • resection of the tumour; • recording of findings in the surgery report/record including visual impression of grade/stage; and • precise description of the specimen(s) for pathology evaluation.	Strong
Performance of individual steps	
Perform *en-bloc* resection or resection in fractions.	Strong
Avoid cauterisation as much as possible during TURB to avoid tissue deterioration.	Strong
Take biopsies from abnormal-looking urothelium.	Strong
Take multiple biopsies (mapping biopsies from the trigone, bladder dome, right, left, anterior and posterior bladder wall) or perform fluorescence-guided (photodynamic diagnosis [PDD]) biopsies, in case of normal upper tract on contrast computed tomography (CT), normal looking urothelium at cystoscopy and positive urine cytology.	Strong

Take a sample of the prostatic urethra if there is positive urine cytology without evidence of tumour in the bladder, or if abnormalities of the prostatic urethra are visible.	Strong
Take a sample biopsy of the prostatic urethra in cases of bladder neck tumour, suspicion of bladder carcinoma *in situ* (CIS) and/or T1 disease. If a sample was not taken during the initial procedure, it should be performed at the time of second resection, if the latter is needed.	Weak
Use methods to improve tumour visualisation during TURB, if available.	Weak
Refer the specimens from different biopsies and resection fractions to the pathologist in separately labelled containers. Submit the tumour base separately, especially in large and multifocal tumours, or when *en-bloc* resection is not feasible.	Weak
The TURB record must describe tumour location, appearance, size and multifocality, all steps of the procedure, extent, macroscopic completeness of resection as well as any complications.	Strong
In patients with positive cytology but negative cystoscopy, exclude an upper tract urothelial carcinoma, CIS in the bladder (by mapping biopsies or PDD-guided biopsies) and tumour in the prostatic urethra (by prostatic urethra biopsy).	Strong

Perform second TURB in the following situations: • after incomplete initial TURB, or in case of doubt about completeness of a TURB; • if there is no detrusor muscle in the specimen after initial resection, with the exception of Ta LG/G1 tumours and primary CIS; or • in T1 tumours.	Strong
If indicated, perform second TURB within two to six weeks after the initial resection. This second TURB should include resection of the primary tumour site.	Weak
Inform the pathologist of prior treatments (intravesical therapy, radiotherapy, etc.).	Strong
The pathological report should specify tumour location, tumour grade and stage, lymphovascular invasion, subtypes of urothelial carcinoma, presence of CIS and detrusor muscle.	Strong

Predicting disease recurrence and progression, and defining risk groups

After TURB, patients should be stratified, according to prognostic factors, into risk groups which will facilitate treatment recommendations (see Table 2). For individual prediction of the risk of tumour progression at different intervals after TURB, use of the 2021 European Association of Urology (EAU) NMIBC risk calculator (www.nmibc.net) is strongly recommended.

For bacillus Calmette-Guérin (BCG)-treated patients, separate scoring models and risk groups have been created by the Club Urologico Español de Tratamiento Oncologico (CUETO) and the

European Organisation for Research and Treatment of Cancer (EORTC)„ respectively. For prediction of tumour recurrence at one and five years in individual patients, the 2006 EORTC scoring model and calculator may be used (https://www.omnicalculator.com/health/eortc-bladder-cancer).

Table 2: Clinical composition of the EAU NMIBC prognostic factor risk groups based on the WHO 2004/2016 or the WHO 1973 grading classification systems

- Only one of the two classification systems (WHO 1973 or WHO 2004/2016) is required to use this table.
- The category of LG tumours (WHO 2004/2016) also includes patients with tumours classified as PUNLMP.
- Additional clinical risk factors are age > 70; multiple papillary tumours; and tumour diameter > 3 cm.

Risk group	
Low Risk	• A primary, single, TaT1 LG/G1 tumour < 3 cm in diameter without CIS in a patient ≤ 70 years • A primary Ta LG/G1 tumour without CIS with at most ONE of the additional clinical risk factors
Intermediate Risk	• Patients without CIS who are not included in either the low-, high-, or very high-risk groups

High Risk	• All T1 HG/G3 without CIS, EXCEPT those included in the very high-risk group • All CIS patients, EXCEPT those included in the very high-risk group
	Stage, grade with additional clinical risk factors: • Ta LG/G2 or T1G1, no CIS with all three risk factors • Ta HG/G3 or T1 LG, no CIS with at least two risk factors • T1G2 no CIS with at least one risk factor
Very High Risk	**Stage, grade with additional clinical risk factors:** • Ta HG/G3 and CIS with all three risk factors • T1 G2 and CIS with at least two risk factors • T1 HG/G3 and CIS with at least one risk factor • T1 HG/G3 no CIS with all three risk factors

The scoring model is based on individual patient data, but does not consider patients with primary CIS, CIS of the prostatic urethra or with recurrent tumours, as well as some pathologic parameters such as subtypes of UC and LVI. Nevertheless, based on data from the literature:

- All patients with CIS in the prostatic urethra, with certain subtypes of UC, or with LVI should be included in the very high-risk group.
- Patients with primary (pure) CIS should be considered in the high-risk group.
- Patients with recurrent tumours should be included in the intermediate-, high-, or very high-risk groups according to their other prognostic factors.

Table 3: Probabilities of disease progression in 1, 5 and 10 year(s) for the EAU NMIBC risk groups*

Risk group	Probability of Progression and 95% Confidence Interval (CI)		
	1 Year	5 Years	10 Years
New Risk Groups with WHO 2004/2016			
Low	0.06% (CI: 0.01%–0.43%)	0.93% (CI: 0.49%–1.7%)	3.7% (CI: 2.3%–5.9%)
Intermediate	1.0% (CI: 0.50%–2.0%)	4.9% (CI: 3.4%–7.0%)	8.5% (CI: 5.6%–13%)
High	3.5% (CI: 2.4%–5.2%)	9.6% (CI: 7.4%–12%)	14% (CI: 11%–18%)
Very High	16% (CI: 10%–26%)	40% (CI: 29%–54%)	53% (CI: 36%–73%)
New Risk Groups with WHO 1973			
Low	0.12% (CI: 0.02%–0.82%)	0.57% (CI: 0.21%–1.5%)	3.0% (CI: 1.5%–6.3%)
Intermediate	0.65% (CI: 0.36%–1.2%)	3.6% (CI: 2.7%–4.9%)	7.4% (CI: 5.5%–10%)
High	3.8% (CI: 2.6%–5.7%)	11% (CI: 8.1%–14%)	14% (CI: 10%–19%)
Very High	20% (CI: 12%–32%)	44% (CI: 30%–61%)	59% (CI: 39%–79%)

WHO = World Health Organization.
** Table 3 does not include patients with subtypes of UC, LVI, CIS in the prostatic urethra, primary CIS or recurrent patients.*
**Please note that these percentages refer to patients who were not (immediately) treated with adjuvant BCG instillations after their primary TURB.*

Recommendations for stratification of non-muscle-invasive bladder cancer (NMIBC)	Strength rating
Stratify NMIBC patients into four risk groups to predict **progression** without bacillus Calmette-Guérin (BCG) therapy, according to Table 2. A patient's risk group can be determined using the 2021 European Association of Urology risk calculator available at www.nmibc.net.	Strong
Use the 2006 European Organisation for Research and Treatment of Cancer (EORTC) scoring model to predict the risk of tumour **recurrence** in individual patients not treated with bacillus BCG.	Strong
Use the 2016 EORTC scoring model or the Club Urologico Español de Tratamiento Oncologico (CUETO) risk scoring model to predict the risk of tumour recurrence and progression in individual patients treated with BCG intravesical immunotherapy (the 2016 EORTC model is calculated for one to three years of maintenance, the CUETO model for five to six months).	Strong

Disease management

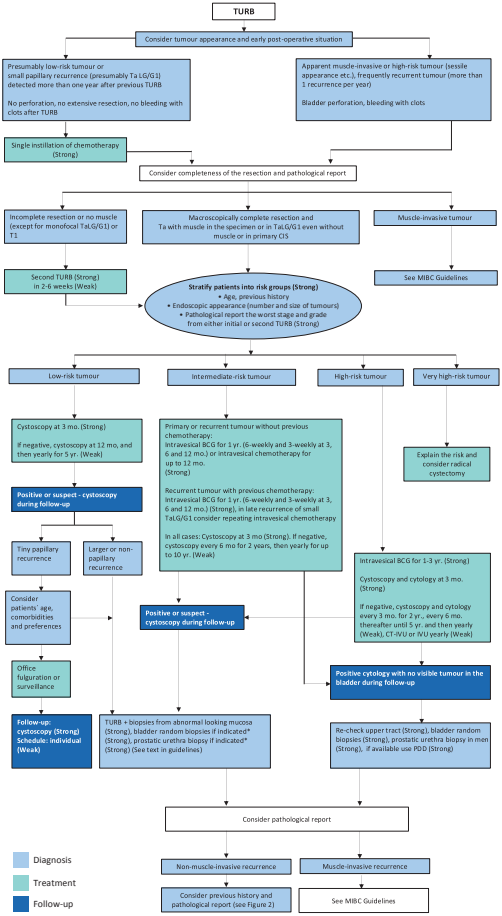
Adjuvant treatment

Since there is considerable risk for recurrence and/or progression of tumours after TURB, adjuvant intravesical therapy is recommended for all stages (TaT1 and CIS).

- **Immediate single post-operative instillation of chemotherapy** after TURB can reduce the recurrence rate in patients with low-risk and selected intermediate-risk tumours. The difference in efficacy between individual drugs (mitomycin C, epirubicin or doxorubicin) has not been confirmed.
- **Further chemotherapy** instillations can improve recurrence-free survival in intermediate-risk tumours, but do not prevent progression. These instillations are associated with minor side effects.
- **Intravesical immunotherapy with BCG** (induction and maintenance) is superior to intravesical chemotherapy in reducing recurrences and in preventing or delaying progression to muscle-invasive bladder cancer.

The individual choice of further intravesical adjuvant therapy depends on the patient's risk (Table 2). In patients at very high risk of progression, immediate radical cystectomy (RC) should be considered.

Figure 1: Treatment strategy in primary or recurrent tumour(s) without previous BCG*



** For details and explanations see the extended NMIBC Guidelines: https://uroweb.org/guidelines/non-muscle-invasive-bladder-cancer.*
BCG = bacillus Calmette-Guérin; CIS = carcinoma in situ; CT = computed tomography; IVU = intravenous urography; MIBC = muscle-invasive bladder cancer; PDD = photodynamic diagnosis; TURB = transurethral resection of the bladder.

Recurrence during or after intravesical BCG therapy

Several categories of BCG failures, broadly defined as any HG recurrence following BCG therapy, have been proposed (Table 4).

Table 4: Categories of high-grade recurrence during or after BCG

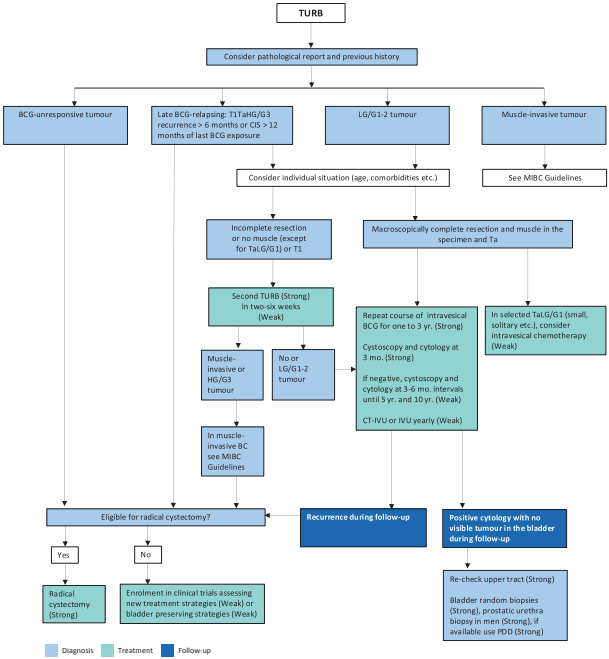
Whenever a muscle-invasive bladder cancer is detected during follow-up.
BCG-refractory tumour
1. If T1 HG/G3 tumour is present at three months. 2. If Ta HG/G3 tumour is present after three months and/or at six months, after either re-induction or first course of maintenance. 3. If CIS (without concomitant papillary tumour) is present at three months and persists at six months after either re-induction or first course of maintenance. If patients with CIS present at three months, an additional BCG course can achieve a complete response in > 50% of cases. 2. If HG tumour appears during BCG maintenance therapy*.
BCG-relapsing tumour
Recurrence of HG/G3 tumour after completion of BCG maintenance, despite an initial response.

BCG-unresponsive tumour
BCG-unresponsive tumours include all BCG refractory tumours and those who develop T1/Ta HG recurrence within six months of completion of adequate BCG exposure** or develop CIS within 12 months of completion of adequate BCG exposure.
BCG-exposed tumour
1. BCG resistant: if Ta HG/G3 or CIS is present at three months evaluation after induction BCG only. 2. Delayed relapse after adequate or inadequate BCG.
BCG intolerance
Severe side effects that prevent further BCG instillation before completing treatment.

* *Patients with LG recurrence during or after BCG treatment are not considered to be a BCG failure.*

** *Adequate BCG is defined as the completion of at least five of six doses of an initial induction course plus at least two out of six doses of a second induction course or two out of three doses of maintenance therapy.*

Figure 2: Treatment strategy in recurrence during or after intravesical BCG



BC = bladder cancer; BCG = bacillus Calmette-Guérin; CIS = carcinoma in situ; HG = high-grade; IVU = intravenous urography; LG = low-grade; MIBC = muscle-invasive bladder cancer; PDD = photodynamic diagnosis; TURB = transurethral resection of the bladder.

General recommendations for adjuvant therapy in TaT1 tumours and for therapy of carcinoma *in situ* CIS	**Strength rating**
Counsel smokers to stop smoking.	Strong
The type of further therapy after transurethral resection of the bladder (TURB) should be based on the risk groups shown in Table 2. For determination of a patient's risk group use the 2021 European Association of Urology risk calculator available at www.nmibc.net.	Strong
In patients with tumours presumed to be at low risk and in those with small papillary recurrences (presumably Ta LG/G1) detected more than one year after previous TURB, offer one immediate single chemotherapy instillation.	Strong
Offer post-operative, saline or water, continuous irrigation of the bladder to patients who cannot receive a single instillation of chemotherapy.	Strong
Patients with small recurrent low-grade (LG) Ta tumours can be effectively and safely offered office fulguration.	Strong
Offer active surveillance and/or chemoablation to selected patients with presumed LG tumours as an alternative to endoscopic ablation.	Weak

In patients with high-risk tumours, full-dose intravesical bacillus Calmette-Guérin (BCG) for one to three years (induction plus three-weekly instillations at 3, 6, 12, 18, 24, 30 and 36 months), is indicated. The additional beneficial effect of the second and third years of maintenance should be weighed against the added costs, side effects and access to BCG. Immediate radical cystectomy (RC) should also be discussed with the patient.	Strong
In patients with very high-risk tumours discuss immediate RC. Intravesical full-dose BCG instillations for one to three years remains an option for selected patients, particularly those who decline or are unfit for RC.	Strong
Discuss the benefits and harms of adding Sasanlimab and Durvalumab to BCG with maintenance in selected BCG-naïve patients with high and very high-risk non-muscle-invasive bladder cancer.	Strong
Offer transurethral resection of the prostate, followed by intravesical instillation of BCG to patients with carcinoma *in situ* (CIS) in the epithelial lining of the prostatic urethra if a bladder-sparing strategy is considered.	Weak
Cautiously offer quinolones to treat BCG-related side effects*.	Weak
The definition of 'BCG-unresponsive' should be respected because it most precisely defines the patients who are unlikely to respond to further BCG instillations.	Strong

Offer an RC to patients with BCG-unresponsive tumours.	Strong
Offer patients with BCG-unresponsive tumours, who are not candidates for RC due to comorbidities or who decline RC, preservation strategies (intravesical chemotherapy, chemotherapy and microwave-induced hyperthermia, electromotive administration of chemotherapy, intravesical- or systemic immunotherapy; preferably within clinical trials).	Weak
Discuss high- and very high-risk patients within a multidisciplinary board, when possible.	Strong
Recommendations - technical aspects for treatment	
Intravesical chemotherapy	
If given, administer a single immediate instillation of chemotherapy within 24 hours after TURB.	Weak
Omit a single immediate instillation of chemotherapy in any case of overt or suspected bladder perforation or bleeding requiring bladder irrigation.	Strong
The optimal schedule and duration of further intravesical chemotherapy instillation is not defined; however, it should not exceed one year.	Weak
If intravesical chemotherapy is given, use the drug at its optimal pH and maintain the concentration of the drug by reducing fluid intake before and during instillation.	Strong

The length of individual instillation should be a minimum of one, and up to two hours.	Weak
BCG intravesical immunotherapy	
Absolute contraindications of BCG intravesical instillation are: • during the first two weeks after TURB; • in patients with visible haematuria; • after traumatic catheterisation; and • in patients with symptomatic urinary tract infection.	Strong

** The side-effect profile of quinolones and fluoroquinolones resulted in the adoption of European regulation restricting their use.*

Recommendations for the treatment of TaT1 tumours and carcinoma *in situ* according to risk stratification	**Strength rating**
European Association of Urology (EAU) risk group: Low	
Offer one immediate instillation of intravesical chemotherapy after transurethral resection of the bladder (TURB).	Strong

EAU Risk Group: Intermediate	
In general, chemotherapy (the optimal schedule is unknown) is a reasonable first-line option in the majority of patients. One-year full-dose bacillus Calmette-Guérin (BCG) treatment (induction plus three-weekly instillations at 3, 6 and 12 months), is an alternative option. The final choice should reflect the individual patient's risk of recurrence and progression as well as the efficacy and side effects of each treatment modality. Offer one immediate chemotherapy instillation to patients with small papillary recurrences detected more than one year after previous TURB.	Strong
EAU risk group: High	
Offer intravesical full-dose BCG instillations for one to three years but discuss immediate radical cystectomy (RC).	Strong
EAU risk group: Very High	
Offer RC or intravesical full-dose BCG instillations for one to three years, particularly to those who decline or are unfit for RC.	Strong

Table 5: Treatment options for the various categories of BCG failure

Category	Treatment options
BCG-unresponsive	1. Radical cystectomy. 2. Enrolment in clinical trials assessing new treatment strategies. 3. Other bladder-preserving strategies in patients ineligible for or refusing RC, including approved new treatment strategies when available.
BCG-relapsing: TaT1 HG recurrence > 6 months or CIS > 12 months of last BCG exposure	1. Radical cystectomy or repeat BCG course according to a patient's individual situation. 2. Enrolment in clinical trials assessing new treatment strategies. 3. Other bladder-preserving strategies.
BCG exposed	1. Repeat BCG course or RC according to a patient's individual situation. 2. Enrolment in clinical trials assessing new treatment strategies.
LG recurrence after BCG for primary intermediate-risk tumour	1. Repeat BCG or intravesical chemotherapy. 2. Enrolment in clinical trials assessing new treatment strategies.

Follow-up

Due to the risk of recurrence and progression, patients with NMIBC require follow-up after treatment. The frequency and duration of cystoscopy and imaging should reflect the individual patient's degree of risk.

Recommendations for follow-up of patients after transurethral resection of the bladder for non-muscle-invasive bladder cancer	**Strength rating**
Base follow-up of TaT1 tumours and carcinoma *in situ* on regular cystoscopy.	Strong
Patients with low-risk Ta tumours should undergo cystoscopy at three months. If negative, subsequent cystoscopy is advised nine months later, and then yearly for five years.	Weak
Patients with intermediate-risk Ta low-grade tumours should undergo cystoscopy at three months. If negative, subsequent cystoscopy can be repeated every six months for two years, and then annually for ten years. The subgroup of patients with intermediate-risk Ta that are high-grade should be followed up as high-risk (see below).	Weak

Patients with high-risk and those with very high-risk tumours should undergo cystoscopy and urinary cytology at three months. If negative, subsequent cystoscopy and cytology should be repeated every three months for a period of two years, and every six months thereafter until five years, and then annually lifelong.	Weak
Take yearly and long-term upper tract imaging (computed tomography [CT] urography) for high-risk and very high-risk tumours.	Weak
During follow-up in patients with positive cytology and no visible tumour in the bladder, mapping biopsies or photodynamic diagnosis-guided biopsies (if equipment is available) and investigation of extravesical locations (CT urography, prostatic urethra biopsy) are recommended.	Strong

This short booklet text is based on the more comprehensive EAU Guidelines accessible on the website: http://www.uroweb.org/guidelines/.