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Harnblasenkarzinom

Nicht-muskelinvasives Harnblasenkarzinom (NMIBC)
Muskelinvasives und metastasiertes Harnblasenkarzinom

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Freigabe: interdisziplinärer Qualitätszirkel
Stand: 07/2026, gültig bis 07/2027
Version 3.2

EAU Guidelines on Non-muscle-invasive Bladder Cancer (TaT1, CIS) – 2026

EAU Guidelines on Non-muscle-invasive Bladder Cancer (TaT1 and CIS)

Limited Update March 2026 ·

Zusammenfassung der Handlungsempfehlungen mit Empfehlungsstärke (Strength rating).
Grundlage: 7 Empfehlungsboxen der Vollversion (88 Seiten), inkl. Original-Abbildungen und Kerntabellen.

Legende: Strong = starke Empfehlung Weak = schwache Empfehlung

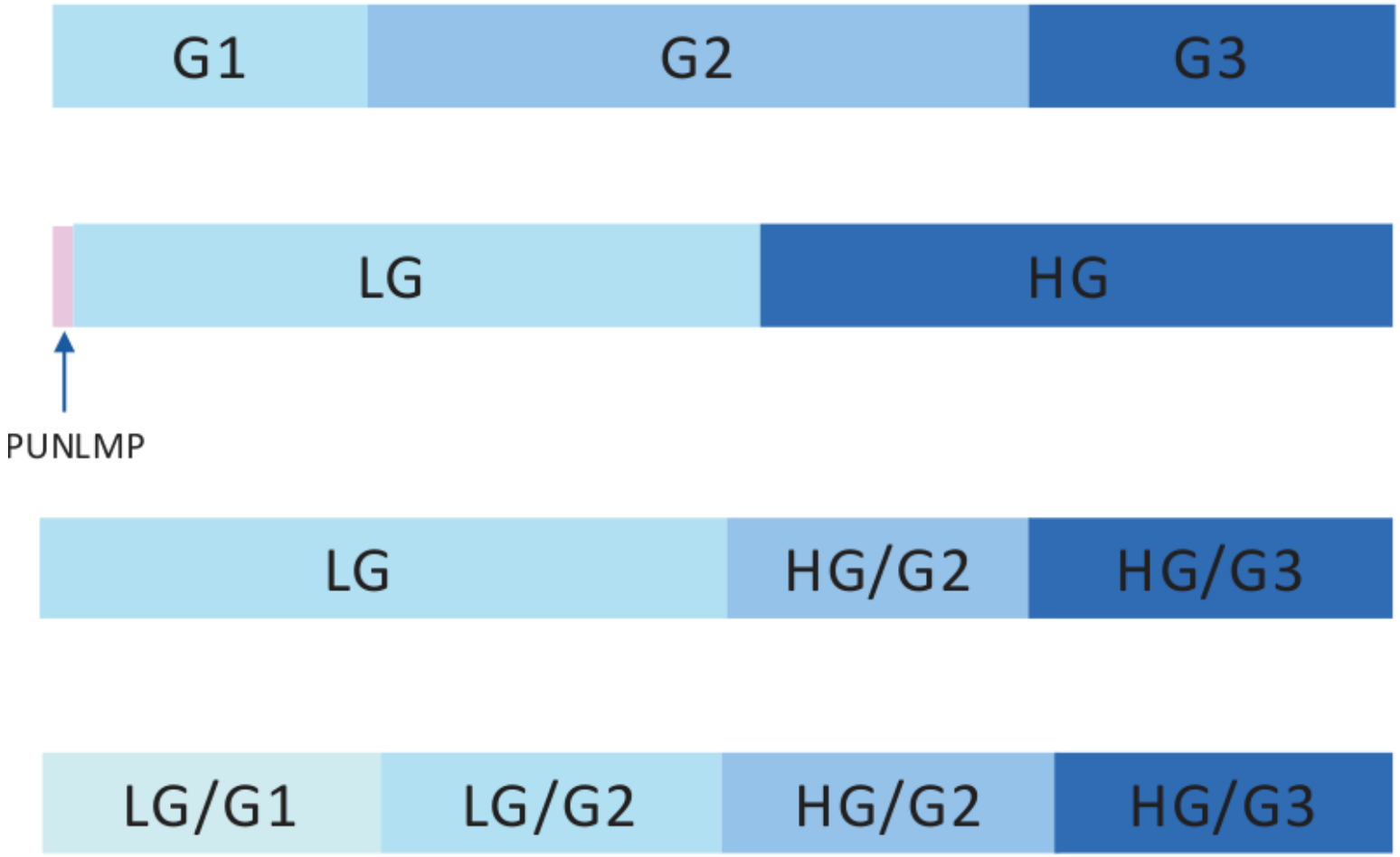
TNM-Klassifikation des Harnblasenkarzinoms – Table 4.1

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

1. Klassifikation & Grading

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

Abb. 4.1: Grading-Schema (WHO 1973 / 2004/2022)



Risikofaktoren für das Harnblasenkarzinom (Table 3.1)

Nature of Risk Factor	Risk Factors	Causality vs. Association
Modifiable	Tobacco smoking, including passive smoking	Causality established
	Occupational exposure: Aromatic amines, polycyclic aromatic hydrocarbons and chlorinated hydrocarbons for e.g. industrial plants which process paint, dye, metal, and petroleum products	
	Diet: • Protective: Flavonoids, mediterranean diet, cruciferous vegetables, fruits*, vitamin B*, high quality diet defined by established dietary indices* • Increased recurrence risk: Vitamin E	Association
	Exercise	
	Obesity (waist-to-hip ratio)	
Non-modifiable	Genetics • 17 susceptibility loci • Detoxification pathways, mainly glutathione S-transferase 1 (GSTM1)	Association
Partly Modifiable	Schistosomiasis	Causality established
	Environmental factors: Chlorination and arsenic exposure to drinking water	Association
	Pelvic radiation	
	Drugs: • Cyclophosphamide • Pioglitazone	

Table 3.1 summarises the main bladder cancer risk factors stratified into modifiable, non-modifiable, and partly modifiable risk categorised according to the existence of an established causality or a mere association with the disease.

** Reported to be protective only in females.*

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2. Primärdiagnostik (Zystoskopie, Zytologie, Marker) (Teil 1/2)

Recommendations	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

2. Primärdiagnostik (Zystoskopie, Zytologie, Marker) (Teil 2/2)

Recommendations	Strength rating
If a magnetic resonance imaging (MRI) is performed for local staging of bladder cancer (BC), it should be done before transurethral resection of bladder tumour (TURBT).	Strong
Perform cystoscopy with or without biopsy confirmation in patients with symptoms suggestive of BC. 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 (see Figure 5.1).	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

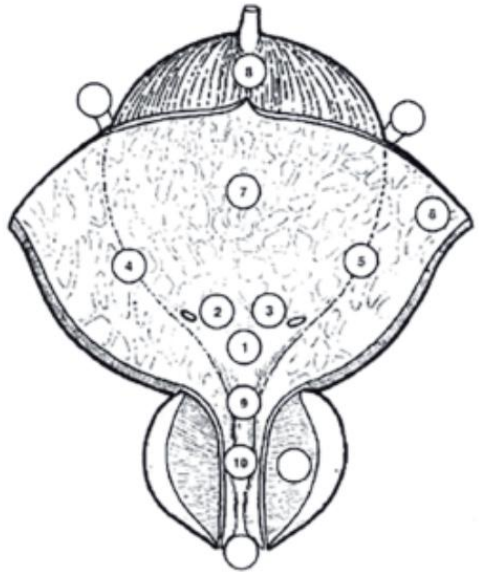
3. TURB, Biopsien & Pathologiebericht (Teil 1/2)

Recommendations	Strength rating
Perform a transurethral resection of the bladder tumour (TURBT) followed by pathology investigation of the obtained specimen(s) as a diagnostic procedure and initial treatment step in patients suspected of having bladder cancer (BC).	Strong
Perform TURBT 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 TURBT 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, 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 (see Section 5.11.2).	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 (see Section 5.11.2).	Weak
Use methods to improve tumour visualisation during TURBT, if available.	Weak

3. TURB, Biopsien & Pathologiebericht (Teil 2/2)

Recommendations	Strength rating
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 TURBT 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 a second TURBT in the following situations: • after incomplete initial TURBT, or in case of doubt about completeness of a TURBT; • 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 a second TURBT within two to six weeks after the initial resection. This second TURBT 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

Abb. 5.1: Blasendiagramm zur Tumordokumentation



1 =Trigone	6 = Anterior wall
2 = Right ureteral orifice	7 = Posterior wall
3 = Left ureteral orifice	8 = Dome
4 = Right wall	9 = Neck
5 = Left wall	10 = Prostatic urethra

5.9 Summary of evidence and recommendations for the primary assessment of non-muscle-invasive bladder cancer

Summary of evidence	**LE**
Cystoscopy with or without biopsy confirmation is necessary for the diagnosis of BC.	1
Urinary cytology has high sensitivity in HG tumours, including CIS.	2b

Recommendations	**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

4. Risikostratifizierung

Recommendations	Strength rating
Stratify non-muscle-invasive bladder cancer (NMIBC) patients into four risk groups to predict **progression** without Bacillus Calmette-Guérin (BCG) therapy, according to Table 6.3. A patient's risk group can be determined using the 2021 European Association of Urology (EAU) risk group 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 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

Prognose nach histologischem Subtyp (Table 6.1)

Prognostic factors in subtypes	Risk of progression
Highly aggressive	
High percentage of subtype(s)	Very high risk of progression
Presence of CIS	
Lymphovascular invasion	
Pure micropapillary, sarcomatoid, nested and plasmacytoid subtype, or NE subtype	
Multifocal tumours	
Residual tumour or incomplete TURBT	
Aggressive	
Absence of CIS and LVI	High risk of progression
Solitary tumour	
Complete TURBT with no residual tumour	

EAU-NMIBC-Risikogruppen 2021 (Table 6.2)

or 1973 WHO grading classification systems [257]

- Only one of the two classification systems (1973 WHO or 2004/2016 WHO) is required to use this table.
- The category of LG tumours (2004/2016 WHO) 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 T1 G1, no CIS with all three risk factors • Ta HG/G3 or T1 LG, no CIS with at least two risk factors • T1 G2 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

Progressionswahrscheinlichkeit nach Risikogruppe (Table 6.3)

[257]*

Risk group	Probability of progression and 95% 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%)

5. Adjuvante Therapie (TaT1 & CIS) (Teil 1/3)

Recommendations - general	Strength rating
Counsel smokers to stop smoking.	Strong
The type of further therapy after transurethral resection of the bladder tumour (TURBT) should be based on the risk groups shown in Section 6.3 and Table 6.1. For determination of a patient's risk group, use the 2021 European Association of Urology (EAU) risk group 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 TURBT, 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 (AS) 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 its 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 remain 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 NMIBC.	Strong
Offer transurethral resection of the prostate, followed by intravesical instillation of BCG, to patients with 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

5. Adjuvante Therapie (TaT1 & CIS) (Teil 2/3)

Recommendations - general	**Strength rating**
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-risk 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 TURBT.	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	

5. Adjuvante Therapie (TaT1 & CIS) (Teil 3/3)

Recommendations - general	Strength rating
Absolute contraindications of BCG intravesical instillation are: • during the first two weeks after TURBT; • in patients with visible haematuria; • after traumatic catheterisation; and • in patients with symptomatic urinary tract infection.	Strong

Management BCG-Nebenwirkungen (Table 7.1, Teil 1)

Management options for local side effects (modified from IBCG)	
Symptoms of cystitis	Phenazopyridine, mirabegrone or NSAIDs.
	If symptoms improve within a few days: continue instillations.
	If symptoms persist or worsen: a. Postpone the instillation b. Perform a urine culture c. Start empirical antibiotic treatment.
	If symptoms persist even with antibiotic treatment: a. With positive culture: adjust antibiotic treatment according to sensitivity. b. With negative culture: quinolones* and potentially analgesic anti-inflammatory instillations once daily for five days (repeat cycle if necessary).
	**If symptoms persist: anti-TB drugs + corticosteroids.
	If haematuria persists, perform cystoscopy to evaluate presence of bladder tumour.
Haematuria	Perform urine culture to exclude haemorrhagic cystitis if other symptoms present.
	If haematuria persists, perform cystoscopy to evaluate presence of bladder tumour.
Symptomatic granulomatous prostatitis	Perform urine culture.
	Quinolones.
	If quinolones are not effective: isoniazid (300 mg/day) and rifampicin (600 mg/day) for three months.
	Cessation of intravesical therapy.
Epididymo-orchitis [391]	Perform urine culture and administer quinolones.
	Cessation of intravesical therapy.
	Orchidectomy if abscess or no response to treatment.
Management options for systemic side effects	
General malaise, fever	Generally resolve within 48 hours, with or without antipyretics.

Management BCG-Nebenwirkungen (Table 7.1, Teil 2)

Management options for local side effects (modified from IBCG)	
Arthralgia and/or reactive arthritis	Rare complication and considered autoimmune reaction.
	Arthralgia: treatment with NSAIDs.
	Reactive arthritis: NSAIDs.
	If no/partial response, proceed to corticosteroids, high-dose quinolones or anti-TB drugs.
Persistent high-grade fever (> 38.5°C for > 48 h)	Permanent discontinuation of BCG instillations.
	Immediate evaluation: urine culture, blood tests, chest X-ray.
	Prompt treatment with more than two antimicrobial agents while diagnostic evaluation is conducted.
	Consultation with an infectious disease specialist.
BCG sepsis	Prevention: initiate BCG at least two weeks post-TURBT (if no signs and symptoms of haematuria).
	Cessation of BCG.
	For severe infection: • High-dose quinolones or isoniazid, rifampicin, and ethambutol 1.2 g daily for six months. • Early, high-dose corticosteroids as long as symptoms persist. • Consider an empirical non-specific antibiotic to cover Gram-negative bacteria and/or *Enterococcus*.
Allergic reactions	Antihistamines and anti-inflammatory agents.
	Consider high-dose quinolones or isoniazid and rifampicin for persistent symptoms.
	Delay therapy until reactions resolve in case of mild (local) reaction. Discontinue BCG in case of moderate- or severe systemic reaction.

6. Therapie nach Risikogruppe

Recommendations	Strength rating
European Association of Urology (EAU) risk group: Low	
Offer one immediate instillation of intravesical chemotherapy after transurethral resection of the bladder tumour (TURBT).	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 TURBT.	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

Abb. 7.1: Therapiestrategie – primär/rezidiv ohne vorheriges BCG

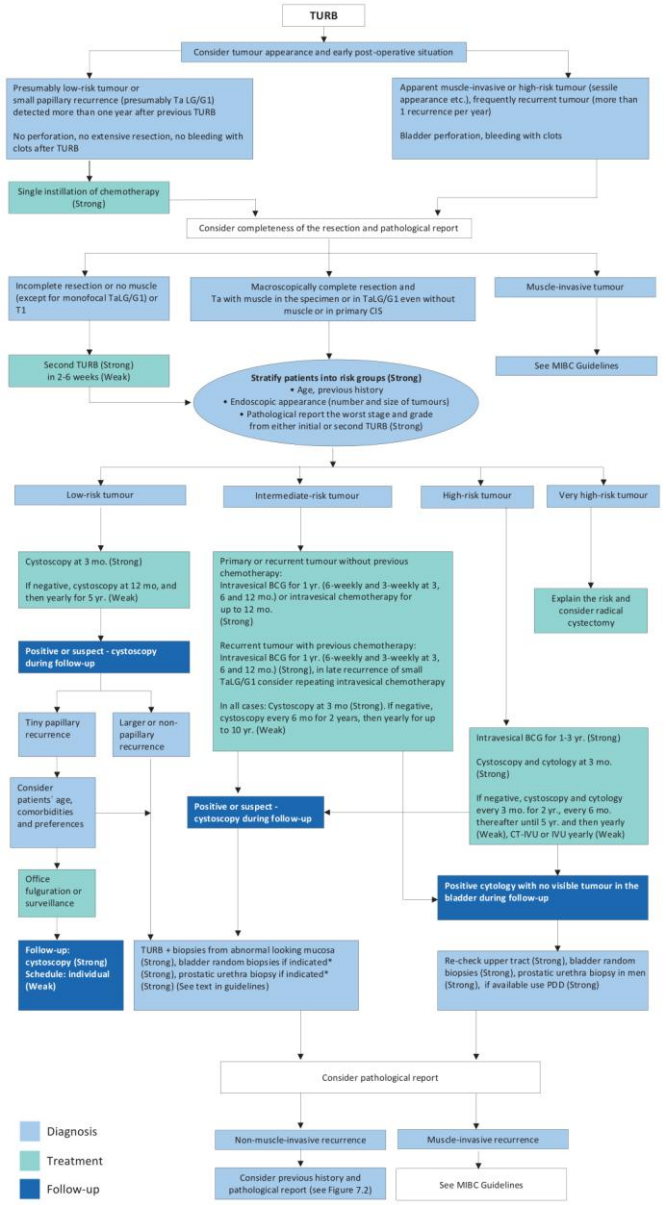


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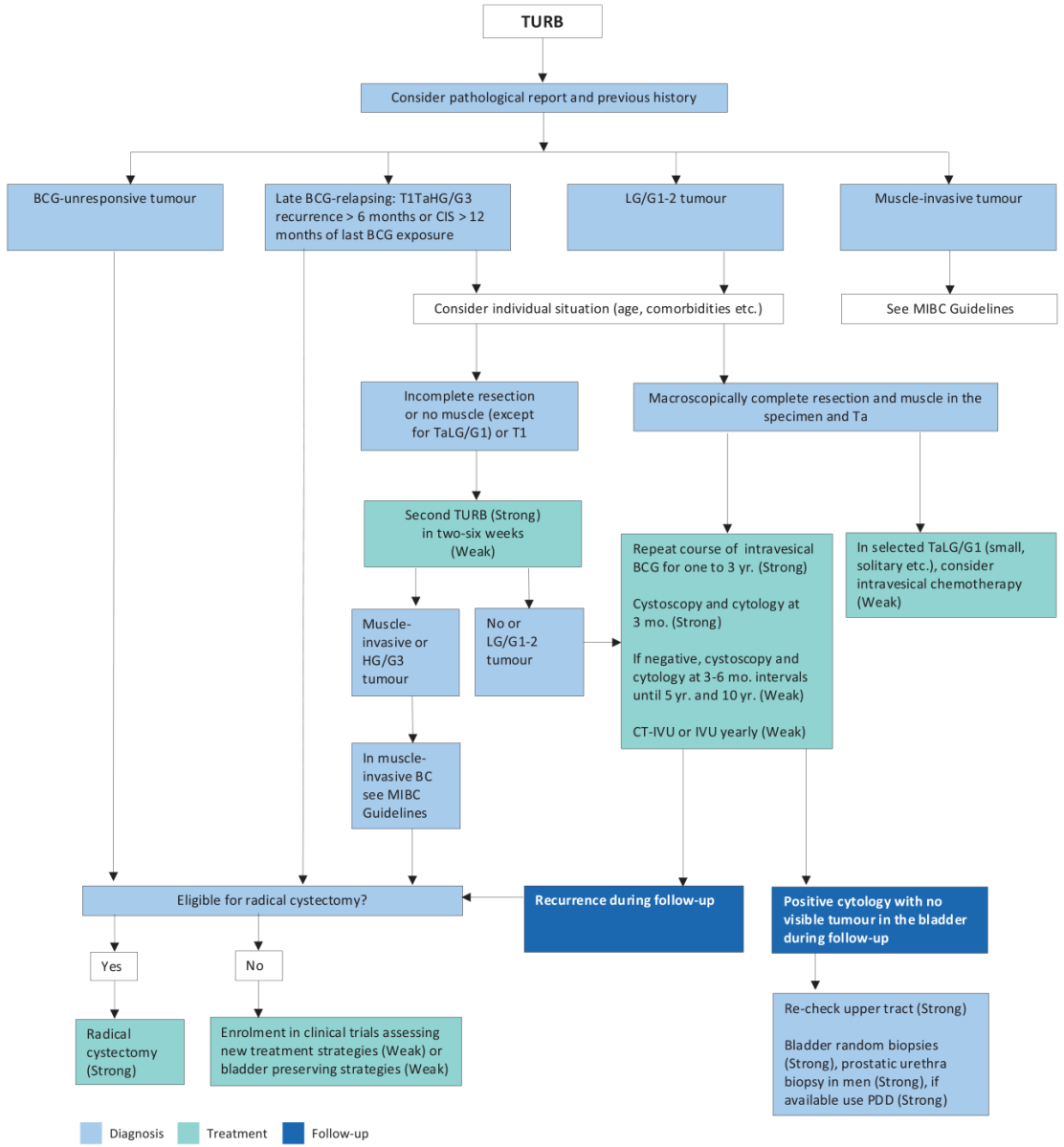
Abb. 7.2: Therapiestrategie – Rezidiv während/nach BCG



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Kategorien des BCG-Versagens (Table 7.2)

Whenever a MIBC is detected during follow-up.
BCG-refractory tumour
1. If T1 HG/G3 tumour is present at three months [454, 455, 460]. 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 [450]. 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 [76, 446, 450]. 4. 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 [461].
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 [456].
BCG-exposed tumour [458, 459]
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 [389].

BCG-unresponsive: Optionen Ta/T1 (Table 7.3)

Papillary Ta/T1								
Compound	**Study design**	**n**	**FU (mo.)**	**DFS (%)**			**PFS**	**≥ Grade 3 adverse events**
				3 mo.	**6 mo.**	**12 mo.**		
Intravesical								
NADOFARAGENE FIRADENOVEC* [484]	Phase III Ta/T1 Cohort NCT02773849	48	20.2	72.9		42.8		G1-2 66.0% G ≥ 3 4%
CREMOSTIMOGENE GRENADENOREPVEC [474]	Phase II BOND II NCT02365818	9		33 Ta 50, T1 0				G1-2 82.5% G ≥ 3 4.5%
N-803 Nogapendekin Alfa Inbakicept + BCG* [486]	Phase II/III QUILT 3032 CB	82	20.7			55.4		G1-2 86% G ≥ 3 23%
TAR 200* [476]	Phase II b SunRISe-1 C4 NCT04640623	52	12.8		85.3	70.2	78.8	Any G 80.8% G ≥ 3 13.5%
RITE [467]	Phase III HYMN NCT01094964	33	36			53 vs. 24 c at 18 mo n/s		G1-2 81%
EMDA-MMC [466]	Phase II	18	35	77.7		72.2		23.1 % local / 11.5 Allergic
Systemic								
PEMBROLIZUMAB* [489]	Phase II Cohort B KEYNOTE-057 NCT02625961	132	45.4	85		43.5% (HR) 41.7%		G1-2 59% G ≥ 3 15%
ATEZOLIZUMAB [471]	Phase II Cohort B SWOG 1605 NCT02844816	55	41	67	53	49	90.9	G1-2 70% G ≥ 3 14%
ERDAFITINIB [490]	Phase II THOR-2 Cohort 1 NCT04172675	73	13.4		96% vs. 73%	77 % vs. 41%		G1-2 100% vs. 83% G ≥ 3 36.7% vs. 0%

BCG-unresponsive: Optionen CIS (Table 7.4)

Carcinoma *in situ* ± papillary								
Compound	**Study design**	**n**	**FU (mo.)**	**Complete response (%)**			**PFS**	**Adverse events**
				3 mo.	**6 mo.**	**12 mo.**		
Intravesical								
NADOFARAGENE FIRADENOVEC* [484]	Phase III Cis Cohort NCT02773849	103	19.7	53.4	40.8	24.3		G3 4%
CREMOSTIMOGENE GRENADENOREPVEC (CG0070) [474]	Phase II	45			58 CIS 50 CIS+P			G1-2 82.5% G ≥ 3 4.5%
N-803 Nogapendekin Alfa Inbakicept + BCG* [486]	Phase II/III QUILT 3032 CA	82	23.9	55.0	56.0	45.0		G1-2 86% G ≥ 3 23%
TAR 200* [476]	Phase II b SunRISe-1 C2 NCT04640623	81	20.2	78.8	58.8	45.9	94.3	Any G 83.5% G ≥ 3 12.9%
RITE [467]	Phase III HYMN NCT01094964	61	36	30 vs. 47				G1-2 81%
EMDA-MMC [466]	Phase II	8	36	62.5		35.5		23.1 % local / 11.5 Allergic
VALRUBICIN* [494, 495]	Phase III	87	30		21			86% Bladder 50% other 20 SAEs 2 TRSAEs
GEMCITABINE DOCETAXEL [483]	Phase II	19	14		75 HR RFS	69 HR RFS	91.4	G1-2 75% G ≥ 3 2.5%
Systemic								
PEMBROLIZUMAB* [488]	Phase II Cohort A KEYNOTE-057 NCT02625961	96	36.4	41.0		18.7		G1-2 53.0% G ≥ 3 13%
ATEZOLIZUMAB [471]	Phase II Cohort A SWOG 1605 NCT02844816	74	41	43	27.0		90.5	G1-2 70.0% G ≥ 3 14%
CETRELIMAB [476]	Phase II b SunRISe-1 C3 NCT04640623	28	29.2			38.5		Any G 53.6% G ≥ 3 7.1%
Combination intravesical and systemic								
CREMOSTIMOGENE GRENADENOREPVEC + PEMBROLIZUMAB [491]	Phase II CORE-001 Trial NCT04387461	35	26.5	82.9%	57.1%	51.4 %		G3 14.3%
TAR 200 + CETRELIMAB [476]	Phase II b SunRISe-1 C1 NCT04640623	53	33.4			55.6		Any G 92.5% G ≥ 3 37.7%

*FDA-approved drug

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Therapieoptionen bei BCG-Versagen (Table 7.5)

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.

7. Nachsorge nach TURB (Teil 1/2)

Recommendations	Strength rating
Base follow-up of TaT1 tumours and carcinoma *in situ* (CIS) 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

7. Nachsorge nach TURB (Teil 2/2)

Recommendations	Strength rating
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

Nachsorge-Schema nach Risikogruppe (Table 8.2)

Risk group	Cytology*	Cystoscopy	Imaging	Duration of follow-up
Low	No	At 3 and 12 months Then annually	Not systematic	5 years
Intermediate (not including HG/G3 subgroup)*	No	At 3 months Then every 6 months for 2 years Then annually	Not systematic	10 years
High and Very High	Yes**	Every 3 months for 2 years Then every 6 months up to 5 years Then annually	Computed tomography (CT) annually up to 5 years, then CT every 2 years up to 10 years Life long	Life long

**Intermediate-risk HG/G3 subgroup should be followed-up as high-risk*

*** At the same intervals as cystoscopy*

Gültigkeit	Datum der Aktualisierung	Version	Änderung	Verantwortliche
März 2017 – März 2019	15.08.2017	1.1	Anpassung des Pathways	Prof. Dr. Schultze-Seemann
Juni 2019 – März 2021	26.08.2019	1.2	Anpassung des Pathways	Prof. Dr. Schultze-Seemann
September 2021 – September 2022	05.10.2021	2	Inhaltliche Aktualisierung des Pathways	Prof. Dr. Schultze-Seemann
November 2022 – November 2023	15.11.2022	2	Verlängerung der Gültigkeit	Prof. Dr. Schultze-Seemann
August 2024 - August 2025	26.08.2024	3.0	Anpassung des Pathways	Prof. Dr. C. Jilg
August 2025 - August 2026	05.08.2025	3.1	Anpassung des Pathways	Prof. Dr. C. Jilg
Juli 2026 – Juli 2027	09.08.2026	3.2	Inhaltliche Aktualisierung des Pathways	Prof. Dr. C. Jilg