NICE National Institute for Health and Care Excellence

NICE guidance

Intravesical microwave hyperthermia and chemotherapy for non-muscle-invasive bladder cancer

HealthTech guidance

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www.nice.org.uk/guidance/htg487

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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 Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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

Contents

This guidance replaces IPG235 and IPG628.

1 Recommendations

1.1 The evidence on the safety of intravesical microwave hyperthermia and chemotherapy for non-muscle-invasive bladder cancer shows there are well-recognised adverse events. Current evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.

1.2 Clinicians wishing to do intravesical microwave hyperthermia and chemotherapy for non-muscle-invasive bladder cancer should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy, alternative treatments and provide them with clear written information. In addition, the use of NICE's information for the public on intravesical microwave hyperthermia and chemotherapy is recommended.
- Audit and review clinical outcomes of all patients having intravesical microwave hyperthermia and chemotherapy for non-muscle-invasive bladder cancer. NICE has identified relevant audit criteria and has developed NICE's interventional procedure outcomes audit tool (which is for use at local discretion).

1.3 Patient selection should be by a specialist bladder cancer multidisciplinary team. The procedure should only be done in specialist centres by clinicians who have had supervised training in the procedure.

1.4 NICE encourages further research into intravesical microwave hyperthermia and chemotherapy for non-muscle-invasive bladder cancer. Research should include randomised controlled trials, which stratify patients by risk and give adequate follow-up. They should report frequency of adverse events, patient-reported

outcome measures, overall and disease-free survival and quality of life.

1.5 NICE may review this procedure on publication of further evidence.

2 The condition, current treatments and procedure

The condition

2.1 Transitional cell carcinoma is the most common form of bladder cancer. Non-muscle-invasive transitional cell carcinoma is classified as stage Ta when the tumour is confined to the uroepithelium with no spread into the bladder wall or beyond. It is classified as stage T1 when there is spread into the connective tissue layer between the urothelium and the muscle wall. Non-muscle-invasive transitional cell carcinomas can be graded from G1 (low grade, least aggressive) to G3 (high grade, most aggressive). Carcinoma in situ is a form of tumour consisting of aggressive cancer cells which spread within the surface lining of the bladder.

Current treatments

2.2 Surgical interventions for non-muscle-invasive transitional cell carcinoma include transurethral resection, in which malignant tissue is removed with an electrocautery device during cystoscopy. Bacillus Calmette-Guérin (BCG) vaccine or chemotherapy drugs may be put directly into the bladder, either as a treatment in itself, or as adjuvant therapy after transurethral resection. Cystectomy may also be necessary in some patients.

The procedure

2.3 Intravesical microwave hyperthermia and chemotherapy can be used as neoadjuvant therapy before transurethral resection, with the aim of eradicating tumours. Alternatively the procedure can be used after transurethral resection, as adjuvant therapy (sometimes referred to as prophylactic treatment), aiming to prevent recurrence. Hyperthermia is believed to have a direct and immune-

mediated cytotoxic effect on tumour cells and to improve the efficacy of chemotherapy drugs.

2.4 The procedure can be done on an outpatient basis. Using local anaesthetic urethral gel, a balloon catheter (containing a radiofrequency antenna and several insulated thermocouples), is inserted through the urethra into the bladder. Ultrasound is sometimes used to assess the position of the device. The radiofrequency antenna gives off microwaves which heat the superficial layers of the bladder wall. The thermocouples are spread out from the catheter and pushed against the bladder lining. They monitor temperature to help prevent overheating. A solution of a cytostatic agent, usually mitomycin C, is instilled into the bladder, between the bladder wall and the balloon surface. The solution is continuously pumped out of the bladder, cooled, and recirculated to prevent overheating. Treatment sessions typically last between 40 minutes and 60 minutes and are usually repeated weekly for 4 to 8 weeks, or longer for adjuvant treatment.

3 Committee considerations

The evidence

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 7 sources, which was discussed by the committee. The evidence included 3 literature reviews, 2 randomised controlled trials (one of which resulted in 2 publications) and 1 case series, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, time to disease progression and progression free survival.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: thermal bladder damage.

3.4 Twelve commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

3.5 The committee was advised that non-muscle-invasive bladder cancer is increasingly being diagnosed in patients where alternative, more invasive treatments such as cystectomy may not be considered clinically appropriate.

3.6 The mechanism of action of intravesical microwave hyperthermia and chemotherapy is unclear. The committee was informed that the microwave energy itself may have some action on the cancer cells.

3.7 The committee noted that the available studies used different treatment protocols, comparators and outcomes. This made interpretation of the evidence

difficult.

3.8 The committee was informed that the technology may be useful when treatment with Bacillus Calmette-Guérin (BCG) vaccine is contraindicated or unsuitable, has been unsuccessful, or when the vaccine is not available.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 628 has been migrated to HealthTech guidance 487. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.